M860

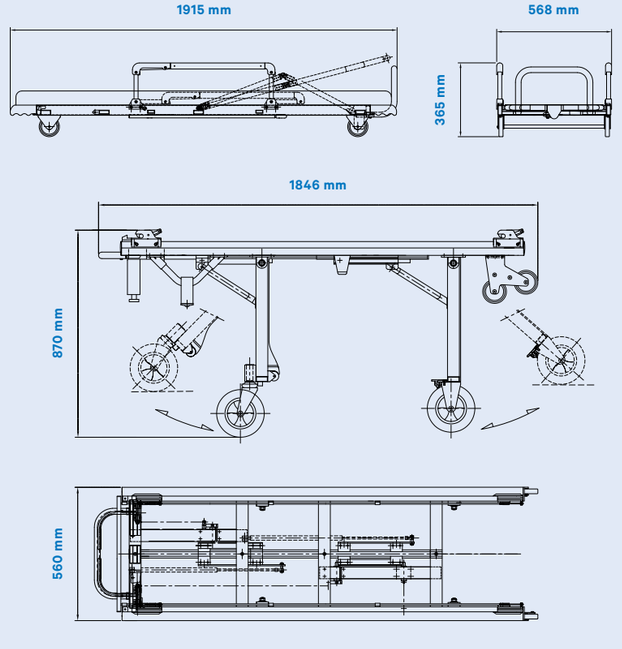
Carucior si targa – separabile

EN 1865-1
10G

Digitally signed by Gorgan Vasile-Dan
Date: 2023.11.22 11:48:16 EET
Reason: MoldSign Signature
Location: Moldova

M**860.** Carucior si targa – separate.

- Structura din aluminiu
- 4 manere telescopice de 75 mm
- 4 roti cu diametru de 200mm (2 pivotante si 2 fixe)
- Spatar ajustabil in opt pozitii
- Suport picioare ajustabil in patru pozitii



EN 1865-1
10G

Greutate:
32,7 kg (carucior)
+ 18 kg (targa)
Capacitate maxima de incarcare:
250 kg
Dimensiuni carucior (inchis):
1846 x 560 x 455 mm
Dimensiuni carucior (deschis):
1846 x 560 x 870 mm
Dimensiuni targa:
1915 x 568 x 365 mm

Dotari:
Suport perfuzii
Manere laterale rabatabile
Centuri fixare mijloc pacient
Centuri fixare peste umar
Centuri de fixare picioare

Garantie:
2 ani

Made in Portugal

AUTO RIBEIRO LDA.

User's Manual:

M860: Trolley and stretcher - Separable

Rua de S. Caetano, 551 Apartado 526
4411-701 Canelas; Vila Nova de Gaia, Portugal
Telf: +351 227157100 , Fax: +351 2271244
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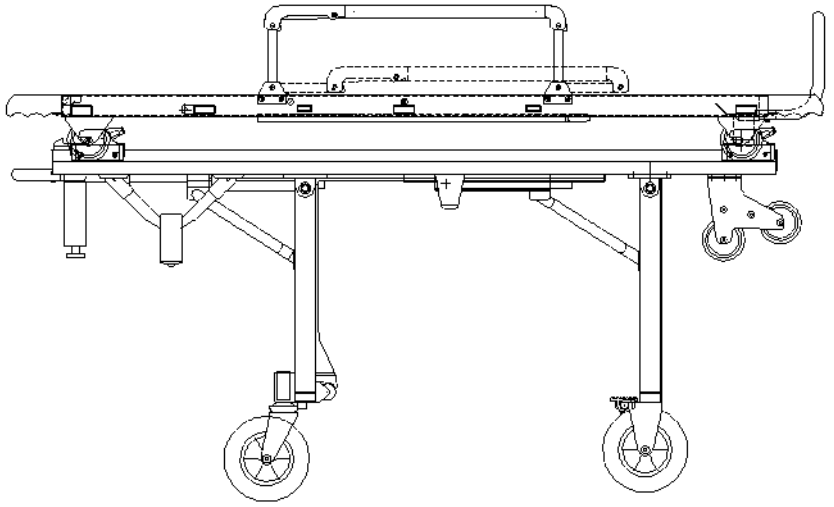
www.autoribeiro.pt



M860: Trolley / Stretcher - Separable

The trolley/stretcher, or M860, is an equipment with separable stretcher of manual drive. This equipment as for main purpose the transport of patients with mobility difficulties and post-operation condition. This product is developed and produced by Auto Ribeiro Lda.

Equipment's Overview

Equipment's Lateral view

ACESSORIES

IV pole

IV pole.

IV pole in use.

Instruments Tray

Instruments tray.

Instruments tray in use.

ACESSORIES

Fixing Restrain Straps

	Shoulder Harness restraints
	Legs and feet restrains

Restraint Installation

	1º - Tying restraint straps in inner bars.
	2º - Pass the restraints through the plate slots
	3º - Join belt buckles..

Top view of Equipment

CHARACTERISTICS:

- Weight: 32,7 kg (trolley) + 18 kg (stretcher)
- Maximum load capacity: 250kg
- Trolley dimensions (closed): 1846 x 560 x 455 mm
- Trolley dimensions (open): 1846 x 560 x 870 mm
- Dimensions (stretcher): 1915 x 568 x 365 mm

FRONT LEG CONTROL (In mid position)

Security System

1º - Lift the lever (put in the right side of trolley).

Final Position.

WHEELS

Swivel Wheels

2 Swivel wheels

Fixed Wheels

2 Fixed wheels

Block of fixed wheels

1º - Engage the tabs with the foot to lock the wheels.

SAFETY WARNINGS

This Equipment can be dangerous:

- Risk of entrapment

ATENTION: USE WITH CAUTION!

- Risk of entrapment

MAINTENANCE

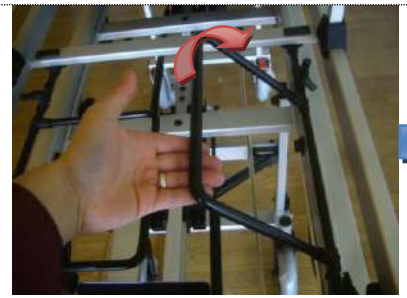
- Perform visual inspection every fifty cycles of utilization.
- Lubrication elements of mechanical function every six months with high viscosity lubricant
- Checking of tightness of binding elements of every three months. Proceed to ajust if necessary

ADJUSTABLE FEET POSITION

Adjustable feet in three different positions:

Footrest and Knees-Flex Position

Lower Legs part Elevation (16º degrees)



Legs Elevation

BACK LEGS CONTROL

Security System

1º - Press the left lever until it moves and keep it pressed.

(Note: To put the back leg into halfway, should press the lever and release it immediately.

FRONT LEG CONTROL

Security System

1º - Press the right lever until it moves and keep it pressed.

STRETCHER BLOCK SYSTEM CONTROL

Security system

1º - Press the lever and keep it pressed.

2º - Press the stretcher to release the trolley.

TELESCOPIC HANDLES

Security System

1º - Press button with finger.

2º - Push or pull to fit the desired length.

SWING DOWN SIDEARMS

Security System

1º - Press button with hand.

2º - Push or pull to achieved the desired opening position.

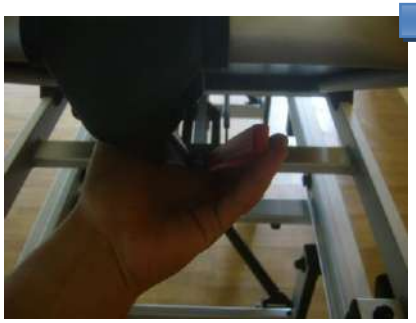
ADJUSTABLE BACKREST

The backrest can be adjusted in different positions:

Supine position

Semi-fowler's Position and Fowler Position

1º - Press the red lever
2º - Push or pull the backrest



MAN AR 42/03/14/00

AUTO RIBEIRO LDA.

Manual de utilizare:
M860: Cărucior și targă - separabile

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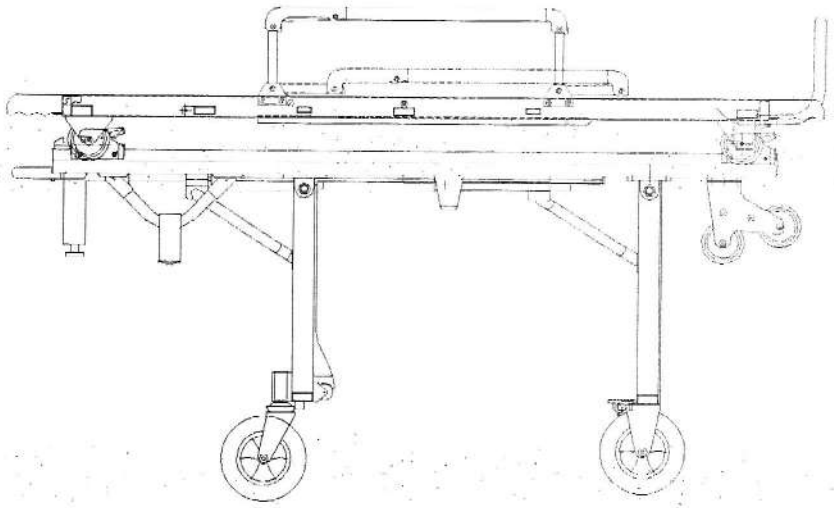
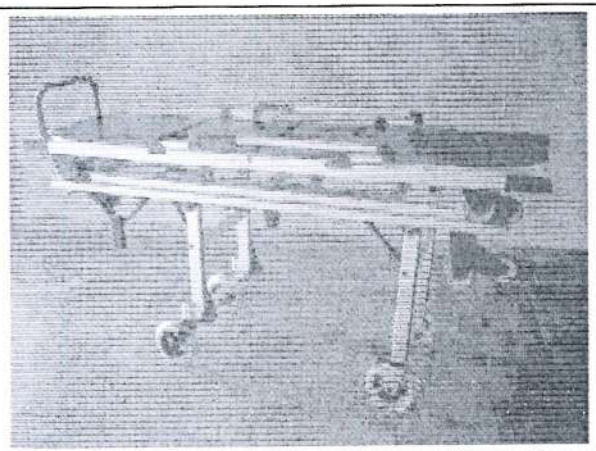
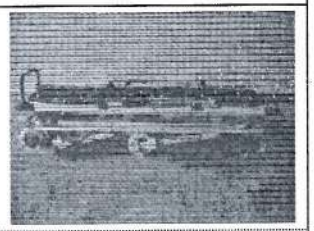


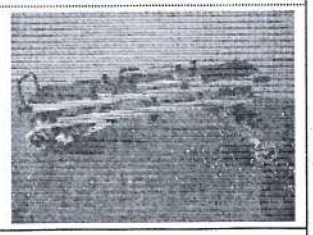
M860: Cărucior / targă - separabile

Targa model M860, este un echipament cu targă separabilă cu manevrare manuală. Destinația sa principală este transportul pacienților cu dificultăți motorii sau aflați în stare postoperatorie. Acest produs a fost dezvoltat și fabricat de Auto Ribeiro Lda.

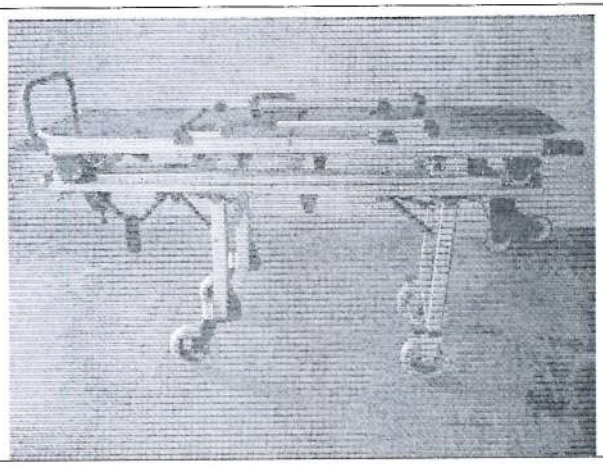
Vedere generală a echipamentului

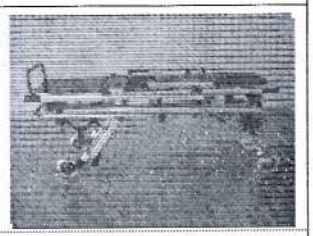


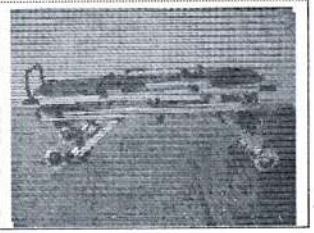




Vedere laterală a echipamentului

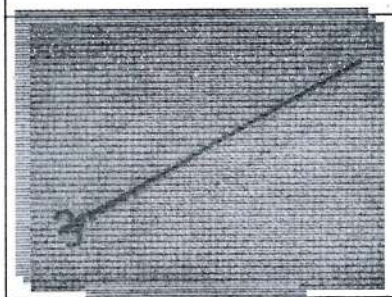




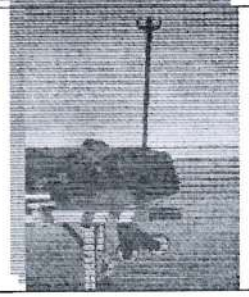


ACCESORII

Stâlp IV

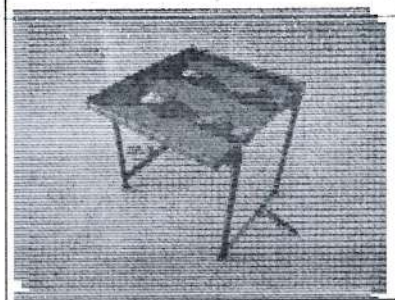


Suport perfuzii



Suportul perfuzii in utilizare

Tava pentru instrumente

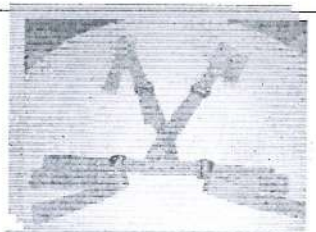


Tava pentru instrumente.

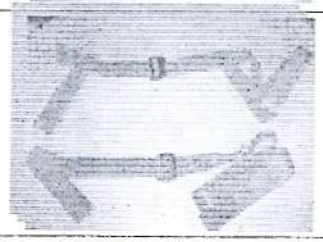
Tava pentru instrumente în uz.

ACESORII

Fixarea centurilor de fixare

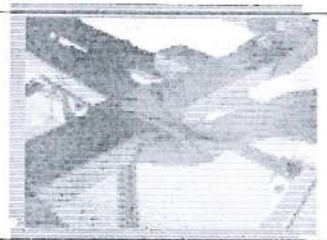


Centuri de fixare umăr

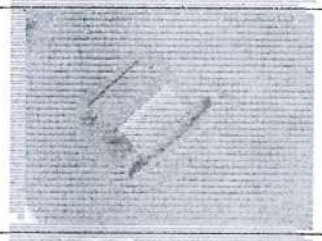


Centuri de fixare picioare și mijloc

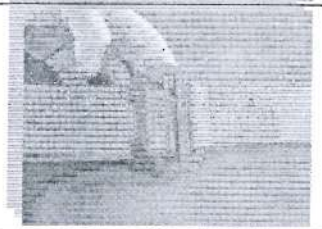
Montarea curelelor de fixare



1° - Legați curelele de fixare de barele interioare.

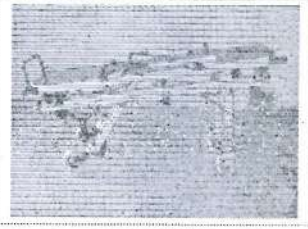


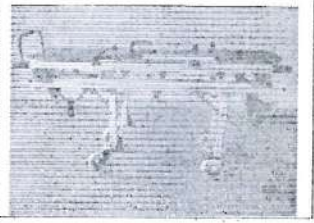
2° - Treceți curelele de fixare prin fantele de pe placă



3° - Cuplați cataramele.

Vedere de sus a echipamentului

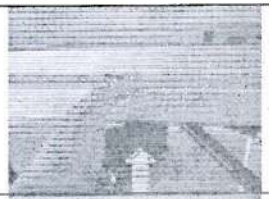
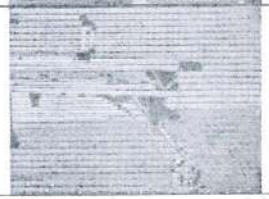




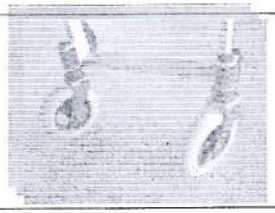
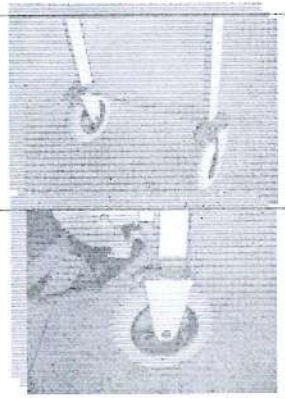
CARACTERISTICI:

- Greutate: 32,7 kg (cărucior) + 18 kg (targă)
- Sarcină maximă: 250 kg
- Dimensiuni cărucior (stare închisă): 1846 x 560 x 455 mm
- Dimensiuni cărucior (stare deschisă): 1846 x 560 x 870 mm
- Dimensiuni (targă): 1915 x 568 x 365 mm

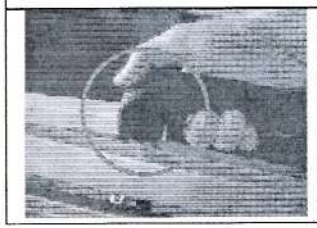
CONTROL PICIOR DIN FAȚĂ (poziția de mijloc)

Sistem de securizare	
	1° - Ridicați maneta (aflată pe partea dreaptă a căruciorului).
	Poziția finală.

ROȚI

Roți pivotante	
	2 roți pivotante
Roți fixe	
	2 roți fixe
	Blocarea roților fixe 1° - Cuplați pedala cu laba piciorului pentru a bloca roțile

AVERTIZĂRI LEGATE DE SIGURANŢĂ

	⚠ **Acest echipament poate fi periculos:** • Pericol de prindere ATENȚIE: A SE UTILIZA CU GRIJĂ!
	⚠ • Pericol de prindere

ÎNTREȚINERE

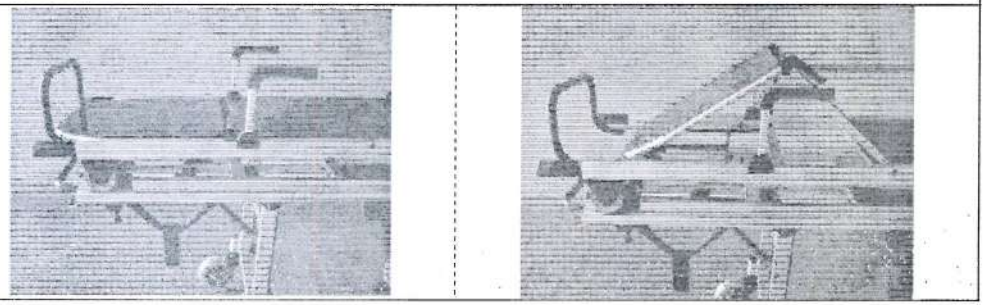
⚠

- A se examina vizual după fiecare cincizeci de cicluri de utilizare.
- Lubrifiați elementele de manevrare mecanică la fiecare șase luni cu lubrifiant de mare vâscozitate.
- Verificați cuplul de strângere al elementelor de legătură la fiecare trei luni. Reglați-le, dacă este nevoie

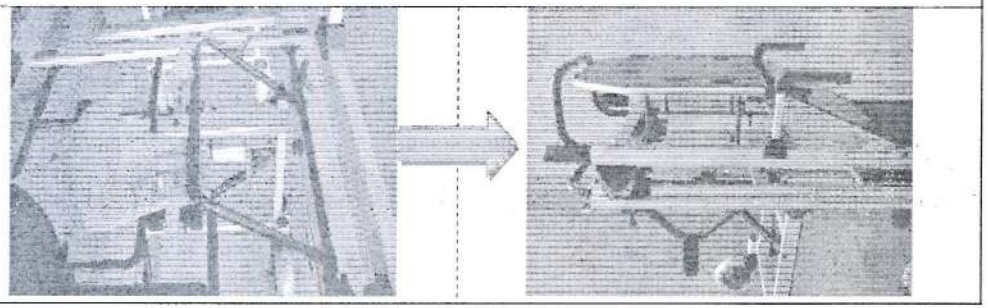
POZIȚIE REGLABILĂ A LABELOR

Labele pot fi fixate în trei poziții:

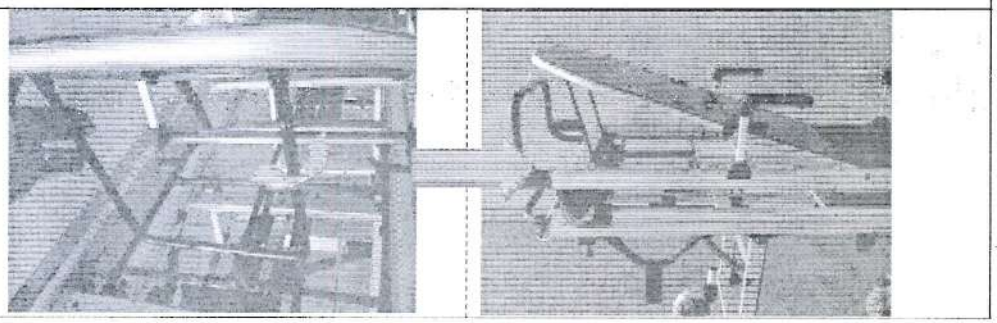
Repaus labe si genunchi flexati



Ridicare partea superioară pentru labe (16°)

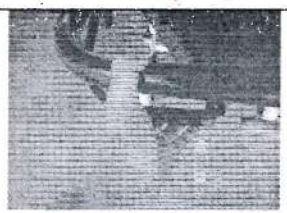


Ridicarea picioarelor



CONTROL PICIOARE DIN SPATE

Sistem de securizare



12° - Apăsați maneta din stânga până când începe să se deplaseze și țineți-o apăsată.

(Notă: Pentru a pune piciorul din spate în poziția de mijloc, apăsați maneta și eliberați-o imediat.

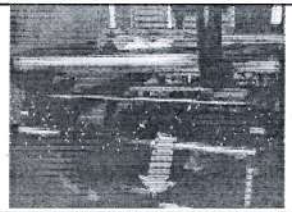
CONTROL PICIOR DIN FAȚĂ

Sistem de securizare

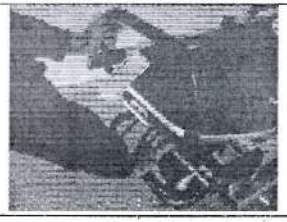
1° - Apăsați maneta din dreapta până când începe să se deplaseze și țineți-o apăsată.

CONTROL SISTEM DE BLOCARE TARGĂ

Sistem de securizare



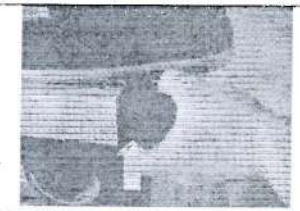
1° - Apăsați maneta din dreapta și țineți-o apăsată.



2° - Apăsați targa pentru a o decupla de la cărucior.

MÂNERE TELESCOPICE

Sistem de securizare

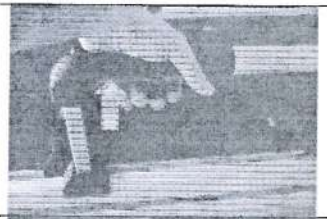


1º - Apăsați butonul cu degetul.

2º - Apăsați sau trageți pentru a-l regla la lungimea dorită.

COBORÂRE BARE LATERALE

Sistem de securizare



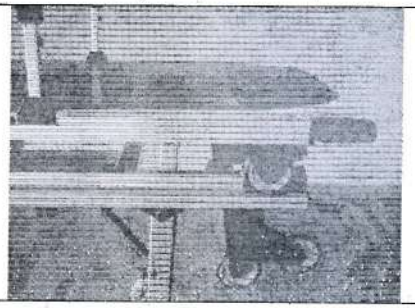
1º - Apăsați butonul cu mâna.

2º - Apăsați sau trageți pentru a-l aduce în poziția deschisă dorită.

SPĂTAR REGLABIL

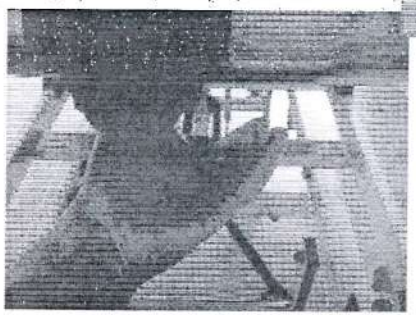
Spătarul poate fi reglat în mai multe poziții:

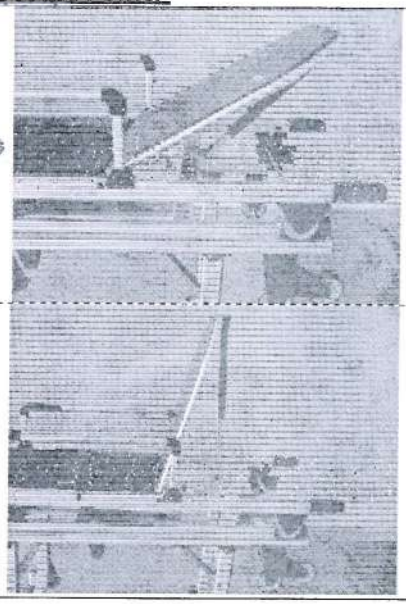
Poziția culcat pe spate



Poziție semi-Fowler și poziție Fowler

1º - Apăsați maneta roșie
2º - Trageți sau apăsați spătarul





Subsemnata **ŞTEFANA FORGACIU**, traducător autorizat de M. J. cu nr. **37629**,
certific exactitatea traducerii în limba română, cu textul înscrisului în copie, în limba engleză.

TRADUCĂTOR **ŞTEFANA FORGACIU** - *AUTORIZAT* cu nr. **37629**

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Portugal

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EU DECLARATION OF CONFORMITY

For medical devices

according to Regulation (EU) 2017/745

CE

Auto Ribeiro Lda., with main facilities at Rua S. Caetano, 459 and 519 – 4411-701 Canelas, Vila Nova de Gaia, Portugal, declares under its own responsibility that the following product according to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 and with the following mentioned standards.

Auto Ribeiro Lda. maintains a Quality Management System that fulfills the requirements of NP EN ISO 9001. Copies of Auto Ribeiro, Lda. ISO 9001 certificate issued by SGS are available upon request.

Product: Carrinho/Maca Amovível

Manufacturer: Auto Ribeiro Lda.

Model: M8

Risk Class of the Device: Class I

Device ID: 393141

Basic UDI-DI: 5600786656TROLLEY68
5600786656STRETCHERC5

CDM: 73573094

Based on Standards:

EN 1865-1	Patient handling equipment used in road ambulance. -Specification for general stretcher systems and patient handling equipment.
EN 1789	Medical vehicles and their equipment – Road Ambulances
EN ISO 9001	System of quality management

Place and date: Canelas - Vila Nova de Gaia, 05-12-2022

Signature

Auto Ribeiro Lda

NIF 500434980

Name: Alexandre Miguel de Oliveira Vila Pouca
(Technical Director)

Auto Ribeiro Lda

DECLARAȚIE DE CONFORMITATE

Producător:	Auto Ribeiro Lda.
Adresa producătorului:	Rua de S. Caetano, 459 e 519 Apartado 526, 4411-701 Canelas V.N. Gaia, Portugalia
Denumirea dispozitivului	Cărucior + targă M860
Destinație:	Transportarea pacienților

Conform EN 1865-1:2010, Auto Ribeiro Lda. declară că echipamentul M860 Cărucior + targă este conform cu toate prevederile aplicabile ale acestui standard.

Auto Ribeiro Lda. sau reprezentantul său va pune la dispoziție, la cerere, toate documentele tehnice aplicabile pentru a permite evaluarea conformității acestui produs cu EN 1865-1:2010.

Auto Ribeiro Lda. menține un Sistem de management al calității care respectă cerințele NP EN ISO 9001. Copiile certificatului ISO al Auto Ribeiro Lda. emise de SGS sunt disponibile la cerere.

José Carlos Barbosa da Silva
Director Calitate

2013

Subsemnata **ŞTEFANA FORGACIU**, traducător autorizat de M. J. cu nr. **37629**,
certific exactitatea traducerii în limba română, cu textul înscrisului în copie, în limba engleză.

TRADUCĂTOR **ŞTEFANA FORGACIU** - *AUTORIZAT* cu nr. **37629**

CERAM
GROUPE UTAC CERAM

Test Report

Reference : N° 15/08190

Applicant	**AUTORIBEIRO,Lda** Rua de S. Caetano N° 551 appartado 526 4411701 CANELAS- V.N GAIA Portugal
Subject	Extension sans essai des brancards AUTORIBEIRO M760, M860 et M764 4SW avec l'ancrage au sol E250, au paragraphe 4.2.10 Fixation de la norme EN1865-1 :2010 +A1:2015. *Extension without test for stretcher AUTORIBEIRO M760, M860 et M764 4SW with floor anchorage E250 products, according with requirements of paragraph 4.2.10 Fixation EN1865-1:2010 +A1:2015 standard*
Department / Test place	Passive Safety Department (SEP) Autodrome de Linas Montlhéry BP 20212 – 91311 Montlhéry Cedex
Test date	13/10/2015
Test Reference	ARCSAS1505907 / AFFSAS1502204
Technician	Nicolas VIE
Summary / Conclusion	Les résultats sont consignés ci-après. The results are consigned after.

Full Name	Nicolas VIE	Jean-Philippe LEPRETRE
Contact	nicolas.vie@utacceram.com +33 (0)1 69 80 34 49	jean-philippe.lepretre@utacceram.com +33 (0)1 69 80 17 32
Function	Project engineer	Passive Safety Unit Manager
Date	13/10/2015	13/10/2015
Signature		

Union Technique de l'Automobile, du Motocycle et du Cycle
Autodrome de Linas-Montlhéry BP 20212 - 91311 Montlhéry Cedex France
Centre d'essais de Mortefontaine Route du golf - 60128 Mortefontaine
Tel : Montlhéry : +33 (0)1 69 80 17 00 / Mortefontaine : +33 (0) 3 44 54 51 51

Société par actions simplifiée au capital de 7 800 000 euros
TVA FR 89 438 725 723- Siren 438 725 723 RCS Evry
Code APE 7120 B

Summary

1 BRANCARD M760 ET FIXATION E250 / STRETCHER M760 AND E250 FIXATION

Type d'essai :
Test type

Extension sans essai suivant le §4.2.10 la norme EN1865-1 :2010 + A1:2015
Extension without test according to paragraph 4.2.10 of EN1865-1:2010 + A1:2015 standard.

Modifications :
Modifications

Modification apportée au brancard :
- Aucune modification apportée au brancard M760 et à la fixation E250.
- Le produit reste identique à celui couvert au travers du rapport UTAC 13/03264

Modification added to the stretcher :
- *No modification added to stretcher M760 and fixation E250.*
- *Product is identical to product cover with UTAC report 13/03264*

Les évolutions de la norme EN1865-1:2010 +A1:2015 des avis de la norme EN1865-1:2010 ne concernent par le paragraphe 4.2.10 Fixation. Le brancard AUTORIBEIRO M760 et sa fixation E250 sont conformes au paragraphe 4.2.10 Fixation de la norme EN1865-1:2010 +A1:2015.

Modifications of EN 1865-1:2010 +A1:2015 standard based on EN1865-1:2010 standard does not concern paragraph 4.2.10 Fixation. The stretcher AUTORIBEIRO M760 and E250 fixation comply with paragraph 4.2.10 EN1865-1:2010 + A1:2015 standard.

2 BRANCARD M860 ET FIXATION E250 / STRETCHER M860 AND E250 FIXATION

Type d'essai :
Test type

Extension sans essai suivant le §4.2.10 la norme EN1865-1 :2010 + A1:2015
Extension without test according to paragraph 4.2.10 of EN1865-1:2010 + A1:2015 standard.

Modifications :
Modifications

Modification apportée au brancard :
- Aucune modification apportée au brancard M860 et à la fixation E250.
- Le produit reste identique à celui couvert au travers du rapport UTAC 13/05648

Modification added to the stretcher :
- *No modification added to stretcher M860 and fixation E250.*
- *Product is identical to product cover with UTAC report 13/05648*

Les évolutions de la norme EN1865-1:2010 +A1:2015 des avis de la norme EN1865-1:2010 ne concernent par le paragraphe 4.2.10 Fixation. Le brancard AUTORIBEIRO M860 et sa fixation E250 sont conformes au paragraphe 4.2.10 Fixation de la norme EN1865-1:2010 +A1 :2015.

Modifications of EN 1865-1:2010 +A1:2015 standard based on EN1865-1:2010 standard does not concern paragraph 4.2.10 Fixation. The stretcher AUTORIBEIRO M860 and E250 fixation comply with paragraph 4.2.10 EN1865-1:2010 + A1:2015 standard.

3 BRANCARD M764 4SW ET FIXATION E250 / STRETCHER M764 4SW AND E250 FIXATION

Type d'essai :
Test type

Extension sans essai suivant le §4.2.10 la norme EN1865-1 :2010 + A1:2015
Extension without test according to paragraph 4.2.10 of EN1865-1:2010 + A1:2015 standard.

Modifications :
Modifications

Modification apportée au brancard :

- Aucune modification apportée au brancard M760 et à la fixation E250.
- Le produit reste identique à celui couvert au travers du rapport UTAC 14/07567

Modification added to the stretcher :

- *No modification added to stretcher M760 and fixation E250.*
- *Product is identical to product cover with UTAC report 14/07567*

Les évolutions de la norme EN1865-1:2010 +A1:2015 des avis de la norme EN1865-1:2010 ne concernent par le paragraphe 4.2.10 Fixation. Le brancard AUTORIBEIRO M764 4SW et sa fixation E250 sont conformes au paragraphe 4.2.10 Fixation de la norme EN1865-1:2010 +A1 :2015.

Modifications of EN 1865-1:2010 +A1:2015 standard based on EN1865-1:2010 standard does not concern paragraph 4.2.10 Fixation. The stretcher AUTORIBEIRO M764 4SW and E250 fixation comply with paragraph 4.2.10 EN1865-12010 +A1: 2015 standard.

GROUPE UTAC CERAM

Raport de încercări

Cod de referință: 15/08190

Solicitant	**AUTORIBEIRO,Lda** Rua de S. Caetano N° 551 appartado 526 4411701 CANELAS- V.N GAIA Portugalia		
Subiect	Extinderea fără testare a brancardei AUTORIBEIRO M760, M860 și M764 4SW cu ancorare în pardoseală E250, conform cerințelor aliniatului 4.2.10 Fixare din standardul EN1865-1:2010 +A1:2015		
Compartiment / Locația încercării	Passive Safety Department (SEP) Autodrome de Linas Montlhéry BP 20212 - 91311 Montlhéry Cedex		
Data încercării	13/10/2015	Cod referință încercare	ARCSAS1505907 / AFFSAS1502204
Tehnician	Nicolas VIE		
Rezumat / Concluzie	Rezultatele sunt consemnate mai jos.		

Nume și prenume	Nicolas VIE	Jean-Philippe LEPRETRE
Date de contact	nicolas.vie@utacceram.com +33 (0)1 69 80 34 49	jean-chilipbe.lepretre@utacceram.com +33 (0)1 69 80 17 32
Funcția	Inginer de proiect	Director Passive Safety Unit
Data	13/10/2015	13/10/2015
Semnătura	*/Semnătură indescifrabilă/*	*/Semnătură indescifrabilă/*

Union Technique de l'Automobile, du Motocycle et du Cycle
Autodrome de Linas-Montlhery BP 20212 - 91311 Montlhéry Cedex France
Centre d'essais de Mortefontaine Route du golf - 60128 Mortefontaine
Tel : Montlhéry : +33 (0)1 69 80 17 00 / Mortefontaine : +33 (0) 3 44 54 51 51

Société par actions simplifiée au capital de 7 800 000 euros
TVA FR 89 438 725 723- Siren 438 725 723 RCS Evry
Code APE 7120 B

Rezumat

1 BRANCARDĂ M760 ȘI FIXARE E250

Tip încercare: *Extindere fără încercare conform aliniatului 4.2.10 al standardului EN1865-1:2010 + A1:2015.*

Modificări: *Modificări adăugate brancardei:*
- *Nicio modificare adăugată brancardei M760 și fixării E250.*
- *Produsul este identic cu produsul din raportul UTAC 13/03264*

Modificările standardului EN1865-1:2010 +A1:2015 pe baza standardului EN1865-1:2010 nu privesc aliniatul 4.2.10 Fixare. Brancarda AUTORIBEIRO M760 și fixarea E250 respectă prevederile aliniatului 4.2.10 din standardul EN1865-1:2010 + A1:2015.

2 BRANCARDĂ M860 ȘI FIXARE E250

Tip încercare: *Extindere fără încercare conform aliniatului 4.2.10 al standardului EN1865-1:2010 + A1:2015.*

Modificări: *Modificări adăugate brancardei:*
- *Nicio modificare adăugată brancardei M860 și fixării E250.*
- *Produsul este identic cu produsul din raportul UTAC 13/05648*

Modificările standardului EN1865-1:2010 +A1:2015 pe baza standardului EN1865-1:2010 nu privesc aliniatul 4.2.10 Fixare. Brancarda AUTORIBEIRO M860 și fixarea E250 respectă prevederile aliniatului 4.2.10 din standardul EN1865-1:2010 + A1:2015.

3 BRANCARDĂ M764 4SW ȘI FIXARE E250

Tip încercare: *Extindere fără încercare conform aliniatului 4.2.10 al standardului EN1865-1:2010 + A1:2015.*

Modificări: *Modificări adăugate brancardei:*
- *Nicio modificare adăugată brancardei M760 și fixării E250.*
- *Produsul este identic cu produsul din raportul UTAC 14/07567*

Modificările standardului EN1865-1:2010 +A1:2015 pe baza standardului EN1865-1:2010 nu privesc aliniatul 4.2.10 Fixare. Brancarda AUTORIBEIRO M764 4SW și fixarea E250 respectă prevederile aliniatului 4.2.10 din standardul EN1865-1:2010 +A1 : 2015.

Subsemnata **ŞTEFANA FORGACIU**, traducător autorizat de M. J. cu nr. **37629**,
certific exactitatea traducerii în limba română, cu textul înscrisului în copie, în limba engleză.

TRADUCĂTOR **ŞTEFANA FORGACIU** - *AUTORIZAT* cu nr. **37629**

GROUPE UTAC CERAM
Autodrome de Linas-Montlhéry
BP 20212 - 91311 Montlhéry cedex France
Forme : PVD.SEP.038.001 R02

ACCREDITATION N°1-0193
PORTEES DISPONIBLES SUR WWW.COFRAC.FR

RAPPORT N°13/05648

DEMANDEUR : **AUTORIBEIRO,Lda**
Rua de S. Caetano
N° 551 appartado 526
4411701 CANELAS- V.N GAIA
Portugal

OBJET : Essais d'étude en vue de la certification du brancard M860 et de la fixation brancard E250, suivant les prescriptions du paragraphe 4.2.10 de la norme EN 1865-1 édition 2010.
Numéro d'affaire : AFFSEP1202602

CONCLUSION : Les résultats d'essais sont consignés ci-après.

MONTLHERY, Le 21 Juin 2013.

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SOMMAIRE

1 BUT DE L'EXTENSION

Essais dynamiques de décélération 10g dans les 4 directions X+, X-, Y(symétrique) et Z+ en vue de la certification du brancard suivant les prescriptions du paragraphe 4.2.10 de la norme européenne EN1865-1 :2010.

Le brancard M860 est défini au travers des plans « MACA P/ CARRINHO M860 » référencés « ARMACARTAMO0011 ACET/AZUL. DES. :D60/001/015 », fournis par AUTORIBEIRO .

2 MATERIEL CONCERNE

2.1 DESCRIPTION DES PIECES

Repère échantillon	Référence constructeur	Désignation	Masses en Kg	Numéro de réception
/	Autoribeiro	Brancard M860 sans matelas	18,95	13Eq053 13Eq076
		Chariot (Undercarriage)	32,65	
		Fixation E250	21,57	

3 ESSAIS DE REFERENCES

3.1 AXES X+ ET X-

Le brancard M860 est couvert suivant les axes X+ et X- par les essais réalisés sur le brancard FERNO F2 au travers du rapport 13/03263 suivant les résultats d'essais des paragraphes 5.2 et 5.3.

Le brancard FERNO F2, similaire au brancard M860 au niveau de la structure longitudinale, est défini au travers des plans « MACA ARM.08/01 » référencés «ARMOMA0014 ACETINADO/PRETO (4 PARTES) OBS. ; Nova Cabeceira. DES. :D60/001/009 ».

Le rail de fixation E250 est couvert suivant les axes X+ et X- au travers du rapport 13/03264 suivant les résultats d'essais des paragraphes 5.1 et 5.5.

3.2 AXES Y (SYMETRIQUE) ET Z+

Le brancard M860 avec son rail de fixation E250 sont couverts suivant les axes Y (symétrique) et Z+ par les essais réalisés sur ce brancard et cette fixation au travers du rapport 13/03563.

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Autodromul Linas Montlhéry
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RAPORTUL NR. 13/05648

SOLICITANT : **AUTORIBEIRO , Lda**
Rua de S. Caetano
Nr. 551, appartado 526
4411701 CANELAS-V. N. GAIA
Portugalia

SUBIECT : Teste de studiu în vederea certificării tărgii M860 şi a fixării tărgii E250, urmând prevederile paragrafului 4.2.10 din norma EN 1865-1, ediţia 2010
Număr de dosar: AFFSEP1202602

CONCLUZIE : Rezultatele încercărilor sunt consemnate în cele ce urmează

MONTHLERLY, la 21 iunie 2013

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Doar versiunea în limba franceză este valabilă.

Prezentul document conţine 3 pagini şi 0 anexe.

UTAC
GROUPE UTAC CERAM

RAPORTUL NR. 13/05648

CUPRINS

UTAC
GROUPE UTAC CERAM

RAPORTUL NR. 13/05648

1. SCOPUL EXTINDERII

Încercări dinamice de decelerare 10 g pe direcţiile X+, X-, Y(simetrică) şi Z+ în vederea certificării tărgii în conformitate cu prevederile paragrafului 4.2.10 din norma europeană EN 1865-1:2010.

Targa M860 este definită în baza planurilor „MACA / P CARRINHO M860", cu referinţa „ARMACARTAMO0011 ACET/AZU. DES:D60/001/015" furnizate de AUTORIBEIRO.

2. MATERIALUL VIZAT

2.1. DESCRIEREA PIESELOR

Reper eşantion	Referinţă constructor	Denumire	Mase în kg	Număr recepţie
/	Autoribeiro	Targă M860 fără saltea	18,95	13Eq053 13Eq076
		Cărucior (şasiu)	32,65	
		Fixare E250	21,57	

3. ÎNCERCĂRI DE REFERINŢĂ

3.1. AXELE X+ ŞI X-

Targa M860 este abordată în ceea ce priveşte axele X+ şi X- de încercările realizate pe targa FERNO F2 în baza raportului 13/03263, conform rezultatele încercărilor de la paragrafele 5.2 şi 5.3.

Targa FERNO F2, similară cu targa M860 în ceea ce priveşte structura longitudinală, este definită în baza planurilor „MACA ARM.08/01", cu referinţa „ARMOMA0014 ACETIBADO/PRETO (4 PARTES) OBS.: Nova Cabeceira. DES :D60/001/009".

Şina de fixare E250 este abordată din punct de vedere al axelor X+ şi X- în raportul 13/03264, conform rezultatele încercărilor de la paragrafele 5.1 şi 5.5.

3.2. AXELE Y (SIMETRICĂ) ŞI Z+

Targa M860 şi şina sa de fixare E250 sunt abordate în ceea ce priveşte axele Y (simetrică) şi Z+ de încercările realizate pe targă şi fixarea sa în baza în raportului 13/03563

Subsemnata **TERTIŞ LARISA DIANA**, traducător autorizat de M. J. cu nr. **16839/2012**,
certific exactitatea traducerii cu textul înscrisului în copie în limba franceză, care a fost vizat de mine.

TRADUCĂTOR **TERTIS LARISA DIANA** - *AUTORIZAT* cu nr. **16839/2012**

TERTIŞ LARISA DIANA
traducător autorizat
franceză - engleză
Aut. M.J. 16839/2012

VM820E & VM820E1 EMS Vacuum Mattresses

The Multi-Chamber-System (VM820E) keeps the beads in the right position and makes application easy and fast

Durable exterior TPU material, easy to clean and disinfect. The red outside consists of fabric double coated with red TPU film. On the inside blue bio-compatible TPU film is facing the patient

Soft and pleasant material facing the patient

Robust, automatically closing valve with adapters for all pumps

Ergonomical, removable heavy duty handles that are easy to clean, reposition or replace

Colour coded patient restraint straps, adjustable from both sides, easy to clean, reposition or replace

An indestructible label with individual serial number and date of manufacture is welded onto every product. Optional are labels with property indicator and distributor logo.

The uniquely thin profile allows for the smallest storage space.

Mattresses with a dimension of 80 x 200 cm need 80 x 45 x 25 cm for storage

ÖSTERREICHISCHES ROTES KREUZ
SALZBURG

SN: VA14X01 90023
www.RedVac.com 01-2009

VM820E is CE certified, complies with EN1865 and is X-ray, CT and MRI compatible.

CE

	**VM820E 30 internal chambers** **VM820E1 1 internal chamber** **Width: 80cm** **Length: 200cm** **Weight: approx. 5,5 kg** **Carry handles: 4** **Patient restraint straps: 4**
	**FP01** **Foot pump** **Material: heay duty plastic** **Length: 43 cm** **Width: 11 cm** **Weight: 0,95 kg**
	**9022** **Repair kit**

KOHLBRAT & BUNZ
Medical systems

Quality Management System
according to
EN ISO 9001:2008 & EN ISO 13485:2003
certified by TÜV Austria

RedVac **made by**

KOHLBRAT & BUNZ GMBH
A-5550 Radstadt Austria
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info@redvac.com www.RedVac.com

VM820E & VM820E1 *Saltele Vacuum SMU*

Sistemul cu mai multe camere (VM820E) menține continutul în poziția corectă și face aplicarea ușoară și rapidă
Material exterior durabil TPU, ușor de curățat și dezinfectat.
Exteriorul roșu este alcătuit din țesătură dublu acoperită cu folie TPU roșie. Pe interior, filmul TPU bio-compatibil albastru este orientat spre pacient

Supapă robustă, cu închidere automată, cu adaptoare pentru toate pompele

Material moale si placut

Mânere ergonomice, detașabile, rezistente, ușor de curățat, repoziționat sau înlocuit

Centuri pacient cu cod de culoare, reglabile din ambele părți, ușor de curățat, repoziționat sau înlocuit

Pe fiecare produs este atasata o eticheta indestructibila cu numarul de serie individual si data fabricatiei.

Opțional sunt etichetele cu indicator de proprietate și sigla distribuitorului.

Profilul unic, subțire permite depozitarea in cele mai inguste spații.

Saltelele cu dimensiuni de 80 x 200 cm au nevoie de un spatiu de depozitare de 80 x 45 x 25 cm

ÖSTERREICHISCHES ROTES KREUZ
SALZBURG

RedVac
CE
SN: VA14X01 90023
www.RedVac.com 01-2009

VM820E este certificat CE, respectă EN1865 și este compatibil cu raze X, CT și RMN.

CE

	**VM820E 30 camere interioare** **VM820E1 1 camera interioara** **Latime: 80 cm** **Lungime: 200 cm** **Greutate: aprox. 5,5 kg** **Mânere de transport: 4** **Centuri pacient: 4**
	**FP01** **Pompă de picior** **Material: plastic rezistent** **Lungime: 43 cm** **Latime: 11 cm** **Greutate: 0,95 kg**
	**9022** **Trusă pentru reparații**

KOHLBRAT & BUNZ
Medical systems

Sistemul de management al calitatii conform EN ISO 9001:2008 & EN ISO 13485:2003 certificat de TÜV Austria

RedVac **fabricat de**

KOHLBRAT & BUNZ GMBH
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KOHLBRAT & BUNZ
GESELLSCHAFT m.b.H.

Konformitätserklärung
Declaration of Conformity

Produktspezifikation / *product details*:

Produktbezeichnung / *product name*	***RedVac Vacuum Mattress***
Type / *type*	**VM820E**
Klassifizierung nach RL 93/42/EWG, Anhang IX / *Classification according 93/42/EEC, Annex IX*	**Klasse I nach Regel 1 / *Class I per rule 1***

Konformitätsbewertung / *assessment details*:

Verfahren nach RL 93/42/EWG / *Route of directive 93/42/EEC*	**Anhang VII (EG-Konformitätserklärung) / *Annex VII (EC Declaration Of Conformity)***

Bewertungs details:

notified body	**SIQ Ljubljana Notified Body ID no. 1304**
Route of directive 93/42/EEC	**Annex VII**
Certificates	**SIQ SI-M-137**

Angewandte Normen / *used standards*:

Harmonisierte Normen / *harmonized standards*	**EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008**
Sonstige Normen / *other standards*:	**EN 1865-1:2010 + A1:2015, EN 1865-2:2010 + A1:2015, EN 1789:2007 + A2:2014**

We declare under sole responsibility that the products described above are in compliance with the applicable requirements of the directive 93/42/EEC as latest amended and of the Austrian medical- device-law BGBl. 657/1996 as latest amended. The products are CE marked.

CE

Radstadt, 27.04.2020

KOHLBRAT & BUNZ Gesellschaft m. b. H.

Ing. Michael Graf QM

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Tel. +43-(0)6452-7193 0 · Fax 7193 51
e-mail: office@kohlbrat-bunz.com
www.kohlbrat-bunz.com

Scaun pliabil pentru transport pacienți Saver, Model S-242

Ușor de manevrat de către două persoane, scaunul pliabil de transport pacienți Saver S-242 își creează cu ușurință loc în spații înguste. Având două roti fixe cu diametrul de 127 mm în partea din spate și două roti frontale pivotante de 76 mm, acesta permite personalului să deplaseze pacientul pe majoritatea suprafetelor, cu un efort minim. Mânerele telescopice din față, cu două opțiuni de poziționare, permit personalului aflat în partea frontală a scaunului să îl manevreze fără a interfera cu zona picioarelor pacientului.

Husa scaunului este fabricată din nailon acoperit cu vinil, ceea ce îl face foarte simplu de curățat, rezistent la pete, sânge și fluide ale corpului.

Scaunul include 3 centuri pentru asigurare pacient.

Dispozitivul de fixare în vehicul este opțional.

Saver Model S-242 ..... **#600100002**

Specificații

	Lungime	Lungime Pliat	Lățime	Înălțime Deschis	Înălțime Pliat	Greutate	Capacitate de Încărcare
Sistem Metric	1210 mm	170 mm	520 mm	915 mm	915 mm	10 kg	159 kg

contact@saver-ems.com / Phone: +(421) (32)778-1072

DECLARATION OF CONFORMITY CLASS I: MEDICAL DEVICE

Product Name	CHAIR S-242 (PACKED) 60-0110-002
Device type	Patient transport
Manufacturer`s Name	FERNO Slovakia, s.r.o.
Manufacturer`s Address	91307 Bosaca 893 Slovakia Tel: 00421-32-7708010-17 Fax: 00421-32-7708011 E: sales@ferno.sk

The undersigned hereby declare that the medical; device specified above has been designated as a Class I device in accordance with the requirements of Annex IX of the EC Directive 93/42/EE concerning medical devices.

Further, it is declared that the device complies with the Essential Requirements in Annexe I of the directive and declaration is made under the requirements of Annex VII of the directive.

Following harmonized standard has been applied:
EN 1865-1: 2012 Specification for stretchers and other patient handling equipment used in road ambulances.
EN 1789:2007+A2:2014 standards for medical vehicles and their equipment – road ambulances.

Device Serial Numbers are identified on the Manufacturing and Inspection Record and/or the Customer Database held at the manufacturers.

FERNO Slovakia
913 07 Bošáca 893
- 01 -

Signed	December 7th, 2017 Date	Ing. Silvia Vančová FULL NAME

Targa antitrauma tip “lopata”

1. Caracteristici si date tehnice:

1.1 Identificare
Targa este identificata printr-o eticheta autoadeziva fixata de structura principala, referitoare la marcajul CE.
Eticheta nu trebuie indepartata. In caz de deteriorare, trebuie sa cereti un duplicat.

1.2 Descriere tehnica
Datorita caracteristicilor sale particulare, targa lopata are un rol important in asistenta acordata pacientilor: permite amplasarea sa sub pacient fara ca acesta sa fie miscat. Totodata, permite imobilizarea pacientului in timpul transportului.
Este dotata cu dispozitive ergonomice si ajustabile, care permit transportul pacientului mentinand o pozitie corecta, chiar si in cele mai dificile conditii, cum ar fi transportul pe scari, pasaje inguste si drumuri cu denivelari.
Targa este confectionata din aluminiu anodizat, iar structura foarte solida confera siguranta in utilizare.

Targa lopata este compusa din:

- Structura principala
- Zona pentru cap
- Zona pentru trunchi
- Zona pentru picioare

Principalele dispozitive sunt:

Dispozitiv de blocare in zona picioarelor
Acest dispozitiv permite ajustarea lungimii totale a targii si blocarea la aceasta dimensiune, in 4 pozitii, in functie de inaltimea pacientului.
Dispozitivul este folosit de asemenea pentru plierea targii in pozitia de depozitare.

Cele doua carlige
Aceste dispozitive permit operatorului sa deschida targa in configuratia dorita (in doua parti sau in pozitie "7"), sa o plaseze sub pacient fara a-l deplasa.

Centuri de siguranta

Aceste dispozitive sunt utilizate pentru a limita miscarile voluntare / involuntare ale pacientului in timpul transportului.
Echipamentul include trei centuri cu deschidere rapida.

1.2 Date tehnice

Inaltime	mm	90
Latime	mm	420
Lungime minima	mm	1670
Lungime maxima	mm	2020
Lungime pliata	mm	1200
Greutate	kg	9,5
Sarcina maxima	kg	170

2. Siguranta
2.1 Directive
Targa antitrauma tip lopata a fost proiectata si este construita respectand prevederile Directivei 93/42/CEE privind dispozitivele medicale si se incadreaza in clasa I.

2.2 Utilizare corespunzatoare si necorespunzatoare
Produsul este destinat uzului profesional intr-o situatie medicala sau de alta natura, constand in transportul, in pozitie orizontala a pacientilor cu patologii corespunzatoare.

Producatorul isi declina responsabilitatea in cazul folosirii produsului in urmatoarele situatii, considerate necorespunzatoare:

- Deplasare executata de personal necalificat.
- Transportul acelor pacienti ale caror patologii au fost definite de catre personalul medical ca necompatibile.
- Nerespectarea regulilor de siguranta de catre operatori.
- Transportul pacientilor a caror greutate depaseste 170 kg.
- Folosirea dispozitivelor care interfereaza cu targa lopata.
- Modificari neautorizate de catre ME.BER.
- Nerespectarea instructiunilor din manual.

2.3 Instructiuni pentru operatori

Produsul a fost fabricat pentru uz profesional. Operatorii, pe langa cunostintele tehnice necesare, trebuie sa aiba sa aiba experienta in folosirea acestui tip de targa.
Pentru a opera in conditii de siguranta si eficienta este necesara implicarea a 2 operatori calificati si cu o buna conditie fizica, pentru a avea forta si coordonarea musculara necesara asigurarii securitatii maxime pentru pacient.
In cazuri particulare, de exemplu in cazul deplasarii pe trepte, rampe, suprafete dificile sau in cazul unui pacient voluminos, este necesara implicarea a doi operatori suplimentari. Ei trebuie sa verifice, inaintea si in timpul transportului, ca pacientul este legat ferm cu ajutorul centurilor.
Schema de mai jos indica numarul de operatori recomandat pentru transportul pacientului, in functie de greutatea acestuia.

Nr/Calificare operatori	**Greutatea pacientului**
2 operatori calificati si antrenati	< 80 kg
2 operatori calificati si antrenati + 1 operator auxiliar	De la 80 la 120 kg
2 operatori calificati si antrenati + 2 operatori auxiliari	De la 120 la 170 kg
Folositi alte modalitati de transport	> 170 kg

Toti operatorii trebuie sa fie pozitionati cu fata catre pacient.
In situatiile care necesita prezenta operatorilor auxiliari, controlul targii si coordonarea transportului sunt in sarcina celor 2 operatori calificati.Toti operatorii trebuie sa fie pozitionati cu fata catre pacient, iar operatorii auxiliari trebuie sa ajute, urmand instructiunile operatorului calificat.

Atentie!
In orice caz, cel putin un operator calificat trebuie sa se afle in permanenta langa pacient, in tot timpul cat acesta este asezat pe targa.

Atentie!
Daca se incalca aceste instructiuni de securitate, se pot produce accidente.

3. Pregatirea utilizarii si instructiuni

3.1 Livrare

Targa este livrata complet asamblata catre beneficiar. Pachetul consta intr-o cutie de carton care contine o punga de plastic si o geanta cu centurile de siguranta.
In momentul receptiei, cumparatorul va verifica daca livrarea este confoema comenii facute. Se va verifica, de asemenea, integritatea targii.

Atentie!

In cazul constatarii unei anomalii, pastrati pachetul si contactati in 48 de ore distribuitorul ME.BER local.

3.2 Depozitare

Daca targa nu este folosita imediat, trebuie depozitata intr-un loc inchis, uscat si curat pentru a pastra in stare de eficienta componentele sale.
Daca mai multe targi trebuie pozitionate una peste alta, recoandam un numar maxim de 10, pentru a evita posibilele deteriorari.

3.3 Pregatirea utilizarii

Targa poate fi folosita numai cand functionarea tuturor componentelor sale este absolut sigura. Pentru aceasta, tehnicieni calificati ME.BER executa teste in tot timpul productiei si un test final, pentru fiecare targa.

Totusi este recomandat ca, inainte de utilizare, sa efectuati o verificare de siguranta, dupa cum este indicat in schema urmatoare:

Descrierea testului	**Rezultat pozitiv**	**Rezultat negativ**
Verificarea profilului in zonele cap/trunchi/picioare		
Deschiderea/inchiderea carligului din zona cap		
Deschiderea/inchiderea carligului din zona picioare		
Verificarea celor 4 pozitii de extensie in zona picioarelor		
Plierea		
Deschidere/inchidere centuri de siguranta		

Daca rezultatul testului este pozitiv, targa este gata de utilizare. Daca nu, contactati reprezentantul ME.BER local.

Atentie!
Pentru a asigura o asigura o eficienta maxima a produsului si cele mai bune conditii de siguranta, testul trebuie repetat periodic.

3.4 Instructiuni de utilizare

Utilizarea targii consta in deschiderea, ajustarea si plasarea sa sub pacient.

Atentie!
Daca exista suspiciunea ca pacientul sufera de traumatisme cervicale, spinale sau lombare, este necesara plasarea sa pe un echipament corespunzator, cum este o placa spinala.

Ajustarea lungimii targii

Lungimea targii poate fi ajustata in 4 pozitii diferite, depinzand de inaltimea pacientului.
Procedati dupa cum urmeaza:

1. asezati targa in pozitie orizontala.
2. asezati-va langa targa, in zona pentru picioare.
3. deschideti dispozitivele de blocare din dreapta si stanga.
4. desurubati cele doua parti pentru picioare si ajustati-le in pozitia dorita, considerand ca lungimea targii poate fi ajustata de la 1670 la 2020 mm in 4 intervale.
5. odata obtinuta lungimea dorita, inchideti dispozitivele de blocare deschise anterior.

Atentie!
Odata executata ajustarea, asigurati-va de blocarea corecta a dispozitivelor de inchidere, verificand ca desurubarea nu mai este posibila.

Deschiderea targii

Pentru a aseza targa sub pacient fara a-l deplasa, este necasara intai deschiderea targii.

Exista cateva tehnici de utilizare a targii lopata, de exemplu inserarea celor doua sectiuni pe rand sub pacient sau deschiderea targii numai in partea dinspre picioare, in forma “7” si plasand partea cealalta sub capul pacientului. Tipul de aplicare trebuie ales in functie de situatie.

Daca doriti sa desfaceti targa in doua parti, procedati dupa cum urmeaza:

1. intindeti targa in pozitie orizontala.
2. asezati-va in partea dinspre cap.
3. tinand in acelasi timp cele doua sectiuni, apasati butonul butonul central al dispozitivului de deblocare si separati-le pana cand ating deschiderea maxima.
4. repetati punctual 2 si 3 pentru a deschide partea picioarelor.

Daca doriti sa deschideti targa in pozitie “7”, deschideti doar carligul partii dinspre picioare.

Asezarea pacientului si inchiderea targii

Urmati procedura dupa cum urmeaza:

Atentie!
In timpul asezarii targii fiti atenti sa nu raniti pacientul sau sa nu ii prindeti in targa parul sau hainele.

Targa deschisa in doua parti

1. Asezati cele doua parti, deja ajustate, intr-o parte si in cealalta a pacientului care urmeaza a fi transportat.
2. Inserati cele doua parti sub pacient, aplicand tehnicile de urgenta necesare, apropiind cele doua parti pana la intalnirea acestora. Blocati mecanismele de inchidere de la cap si picioare.

3. Legati pacientul cu centurile de siguranta, ajustand lungimea lor. Daca este necesar, aplicati un guler cervical.

Targa deschisa in pozitie de “7”

1. Asezati partea dinspre cap a targii, ajustata deja, langa capul pacientului, astfel incat capul pacientului sa se afle in interiorul targii.
2. Inserati capatul targii sub capul pacientului, aplicand tehnicile indicate in medicina de urgenta.
3. Inserati celelalte parti ale targii sub pacient, apropiind cele doua sectiuni pana cand acestea se intalnesc si fixati dispoitivul de blocare.

4. Legati pacientul cu ajutorul centurilor de siguranta si, daca este necesar, aplicati un guler cervical.

Atentie!
Dupa inchiderea celor doua parti, asigurati-va ca toate dispoitivele de inchidere sunt fixate corespunzator (carligele de la extremitatile pentru cap si picioare, dispozitivul de inchidere si centurile de siguranta)

Neutilizarea centurilor de sigutranta poate duce la ranirea pacientului. Asigurati-va ca centurile sunt bine stranse inainte de fiecare utilizare.
Transportul pacientului impune de obicei implicarea a doi operatori calificati. In anumite situatii, se impune implicarea a mai mult de doi operatori.

Pastrare

Targa lopata, fiind construita din materiale rezistente la rugina este usor de intretinut si nu necesita conditii deosebite de depozitare. Totusi, este indicat sa fie tinuta intr-o incinta acoperita, avand grija ca mecanismele de blocare si partile care se misca sa nu se blocheze din cauza patrunderii prafului.
Targa lopata poate fi pliata urmand pasii:

1. intindeti targa in pozitie orizontala
2. asezati-va langa targa, in zona pentru picioare
3. deschideti dispozitivele de blocare dreapta si stanga si desurubati complet cele doua parti in acelasi timp
4. pliati targa, suprapunand partea pentru picioare peste cea pentru trunchi
5. asezati targa in locul dorit

4. Intretinere

Intretinere periodica

Pentru mentinerea targii in stare de perfecta functionare este necesara intretinerea sa periodica.

In cazul in care veti gasi o parte in neconcordanta cu componenta originala a produsului, scoateti targa din uz pana la remedierea defectiunii.
Schema propusa pentru intretinere depinde de frecventa cu care este folosita targa:

Interventie	Interventii /luna <25	<200	>200
Inspectie generala si verificarea functionarii tuturor dispozitivelor	6 luni	3 luni	1 luna
Curatare	Depinde de locul de utilizare si patologia pacientului transportat		
Lubrifierea partilor in miscare	3 luni	2 luni	1 luna

Atentie!
Utilizarea necorespunzatoare poate duce la ranirea pacientului sau operatorilor si la pagube materiale.

Efectuati intretinerea periodica urmand indicatiile manualului.

4.2 Curatare

Urmati indicatiile:

Partile metalice
Spalati cu un burete cu apa si sapun neutru si, daca este necesar, cu dezinfectant. Clatiti si uscati cu atentie. Dupa aceea, aplicati un strat de ceara de protectie.

Partile de plastic
Curatati cu un burete cu solutie dezinfectanta slaba, apoi clatiti si uscati complet.

Atentie!
Evitati folosirea agentilor agresivi – amoniac, inalbitor si a agentilor abrazivi.

4.3 Lubrifiere

Poate fi executata aplicand peste partile in miscare cate doua picaturi de ulei de vascozitate medie.

DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY

Il fabbricante *The manufacturer*	**MEBER S.r.l. Unipersonale** **Via Langhirano, 270** **43124 FONTANINI (PR) ITALY**
Dichiara sotto la propria responsabilità che il dispositivo *Declare under own responsibility that the device*	**'MAXIMA' BARELLA A CUCCHIAIO ANODIZZATA GRIGIA CON TESTA/TRONCO AD 1 PZ. - CERTIFICATA EN 1865 ART. 631** ***'MAXIMA' GREY ANODIZED SCOOP STRETCHER WITH TRUNK/HEAD IN ONE PIECE -EN 1865 CERTIFIED ART. 631***
Classificazione dispositivo (Direttiva 93/42/CEE Allegato IX) *Device Classification (MDD 93/42/EEC Annex IX)*	**Classe I** ***Class I***
È conforme a quanto richiesto dalla Direttiva 93/42/CEE (emendata con Direttiva 2007/47/CE) recepita con D. Lgs. 24 febbraio 1997 n.46 (emendato con D. Lgs. 25 gennaio 2010 n.37) *Is in accordance with MDD 93/42/EEC (amended with Directive 2007/47/EC)*	
Procedimento di valutazione della conformità *Conformity assessment procedure*	**MDD 93/42/CEE (emendata 2007/47/CE) - Allegato VII** ***MDD 93/42/CEE (amended 2007/47/CE) - Annex VII***
Norme armonizzate e/o nazionali applicate, altre norme applicate: *Applied harmonised and/or national standard, other applied norms*	**EN 1865-1:2010+A1:2015** **EN 1789:2010+A2:2014**
Organismo notificato *Notified body*	**n.a.**

Fontanini, 29/04/2019

MEBER Srl Unipersonale
Legale Rappresentante / Legal representative
ANDREA BERTOZZI

N.B. Il documento è valido 5 anni dalla data di emissione
The present document is valid 5 years from the date of issue

9010 Galaxy

"GALAXY" Yellow spinal board

FEATURES

Spinal board made of plastic material at high strength. Designed paying particular attention to the difficulties met during every day's interventions; they have 4 holes for the quick and total fixing of the head immobilizer and two cavities where the board lays on the floor, when the base is blocked in the traditional way, that allow to avoid damages to the rip-off straps during the usage of the spinal board or the accommodation in the ambulance. It has 12 handles for the transport and is supplied with 3 belts with rapid unhooking buckle (Art. 605/MEB). X-ray translucent and available in 3 different colours: yellow, orange and red.

Device certified according to the European harmonized safety standards UNI EN 1865

CARATTERISTICHE TECNICHE

Size	Adults
Length (cm)	183
Width (cm)	41
Thickness (cm)	5
Weight (kg)	5,5
Loading capacity (kg)	150
Trauma	☑
Usage	Immobilization
Material	ABS

SEE ALSO

Galaxy 9016
"GALAXY" Red spinal board

Galaxy 9012
"GALAXY" Orange spinal board

ACCESSORIES

Xeros 625
Adjustable universal head immobilizer

Jelly 629
Orange standard head immobilizer for spinal board

12144/N
Carrying case for spinal board

Spider 690
Belts immobilization system Spider for spinal board

STANDARD ACCESSORIES

605/MEB
50 mm orange belt in one piece with plastic buckle and ME.BER. ribbon

DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY

Il fabbricante *The manufacturer*	**MEBER S.r.l. Unipersonale** **Via Langhirano, 270** **43124 FONTANINI (PR) ITALY**
Dichiara sotto la propria responsabilità che il dispositivo *Declare under own responsibility that the device*	**"GALAXY" TAVOLA SPINALE GIALLA CERTIFICATA EN 1865** **ART. 9010** ***"GALAXY" YELLOW SPINAL BOARD EN 1865 CERTIFIED*** ***ART. 9010***
Classificazione dispositivo (Direttiva 93/42/CEE Allegato IX) *Device Classification (MDD 93/42/EEC Annex IX)*	**Classe I** ***Class I***
È conforme a quanto richiesto dalla Direttiva 93/42/CEE (emendata con Direttiva 2007/47/CE) recepita con D. Lgs. 24 febbraio 1997 n.46 (emendato con D. Lgs. 25 gennaio 2010 n.37) *Is in accordance with MDD 93/42/EEC (amended with Directive 2007/47/EC)*	
Procedimento di valutazione della conformità *Conformity assessment procedure*	**MDD 93/42/CEE (emendata 2007/47/CE) - Allegato VII** ***MDD 93/42/CEE (amended 2007/47/CE) - Annex VII***
Norme armonizzate e/o nazionali applicate, altre norme applicate: *Applied harmonised and/or national standard, other applied norms*	**EN 1865-1:2010**

Fontanini, 29/04/2019

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The present document is valid 5 years from the date of issue

DAVIS

Traction/immobilization system

Davis traction systems are devices that limit tissue damage caused by possible bone rubbing by spacing the two halves of a fracture.

Specific features
Sturdy and lightweight structure
4 padded supports offer greater comfort and a better weight distribution
Elastic immobilization bands
Padded and adjustable ankle band
Soft ischial padding increase leg stability and patient comfort
Transport bag with pocket and strap closure allows easy storage of the device and accessories

Technical data	
Minimum length[(1)]	890 ± 10 mm
Maximum length[(1)]	1350 ± 10 mm
Width	210 mm
Base width	230 mm
Width of leg support area	165 mm
Traction belt length	From 0 to 500 mm
Inclination	10° (variable depending on the extension)
Materials	Steel, Al, Nylon
Weight	1.78 ± 0.1 kg
Bag dimensions	990 x 330 mm
Bag weight	520 g

[(1)] The limb must be approximately 15 cm shorter than the indicated measurements

Sizes subject to ± 10 mm tolerances

Standard equipment
Transport bag

Class I MD compliant with UE Reg. 2017/745	
DAVIS ADULT TRACTION SYSTEM	CE
SR01010A	
CND Classification	V9099
Registration number	195373

Nato stock N° 6515-15-149-2408

Rev.0 (10/09/2021)
UNCHECKED COPY – further revisions will be available on http://support.spencer.it
Spencer Italia S.r.l. Sala Baganza (PR) Italia Tel. +39.0521.541111 Fax +39.0521.541222
www.spencer.it

EU DECLARATION OF CONFORMITY/ *DICHIARAZIONE DI CONFORMITA' UE*

Regulation/Regolamento UE 2017/745

The declaration is released under the sole responsibility of the manufacturer
La dichiarazione è rilasciata sotto la responsabilità esclusiva del fabbricante

Manufacturer/*Fabbricante:*	**Spencer Italia s.r.l.** Via Provinciale, 12 – 43038 Sala Baganza (PR) – Italy
Unique registration number/ *Numero di registrazione unico:*	Eudamed is not active/ *Banca Eudamed non attiva*
Medical Device/*Dispositivo Medico:*	DAVIS ADULT TRACTION SYSTEM/ *DAVIS SISTEMA DI TRAZIONE ADULTO*
Code /*Codice:*	SR01010A
BASIC UDI-DI /*UDI-DI di base:*	805771123SISTEMATRAZKU
Lot/ *Lotto* SN/ *Matricola*	Not available before the production/ *Non disponibile prima della produzione*
Quantity/*Quantità:*	1
Risk class /*Classe di rischio:* (Annex VIII/*Allegato VII)*	I
Conformity assessment procedure/ *Procedura valutazione conformità*	Not present /*Non presente*
Rule/*Regola:*	1

Spencer Italia S.r.l. declares under its sole responsibility that the above mentioned medical device is in compliance with the requirements of the Regulation 2017/745 and with the applicable regulations and common specifications.
Spencer Italia S.r.l. *dichiara sotto la sua sola responsabilità che il Dispositivo Medico sopra menzionato, è conforme ai requisiti del Regolamento 2017/745, alle norme e alle specifiche comuni applicabili.*

The list of applicable standards is reported in the Technical File.
La lista delle norme applicabili è riportata nel relativo Fascicolo Tecnico.

Sala Baganza (PR) - IT, 03/04/2022

First name and surname /*Nome e cognome:*_____

Role/*Ruolo:* _____ Signature/*Firma:*_____

Person in whose name and on whose behalf this declaration of conformity has been signed/
Persona a nome e per conto della quale è stata firmata la presente Dichiarazione UE :

Antonio Ciardella
(Legal Representative /*Legale Rappresentante)*

SET RES-Q-SPLINT

Atele vacuum – Set 3 dimensiuni cu pompa si geanta

Atelele Res-Q-Splint sunt dispositive folosite la imobilizarea membrelor în cazul suspiciunii de leziuni sau fracturi ale acestora.

Trasaturi specifice
Folie PVC usor de curatat
Canalele separate evită mișcarea și acumularea materialului de umplutură, asigurând o mai bună distribuție a acestuia, făcând mai eficientă imobilizarea membrului
Închidere rapidă datorită centurilor velcro
Supapa unisens caracterizată prin pasaje care permit volume mari de aer, astfel se atinge mai repede nivelul de vid dorit
Geantă de transport cu mânere și suport pentru pompă pe partea din spate; pompa furnizată se caracterizează prin dimensiuni reduse și eficiență ridicată

Date tehnice	
Dimensiuni marime S	560 x 460 ± 10 mm
Dimensiuni marime M	490 x 380 x 700 ± 10 mm
Dimensiuni marime L	750 x 540 x 900 ± 10 mm
Greutate marime S	295 ± 50 g
Greutate marime M	630 ± 50 g
Greutate marime L	1050 ± 50 g
Dimensiuni geanta	550 x 410 x 160 ± 20 mm
Materiale	PVC, Al, PS
Greutate set	3,16 ± 0,2 kg

QM22500A
RES-Q-SPLINT - SET 3 DIMENSIUNI CU POMPA SI GEANTA

SET format din urmatoarele DM conform Reg. UE. 2017/745		
QM22530A – Atela vacuum marime S cu camere separate	Reg. n. 102933	CND V0804
QM22520A – Atela vacuum marime M cu camere separate	Reg. n. 102924	CND V0804
QM22510A – Atela vacuum marime L cu camere separate	Reg. n. 102852	CND V0804

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www.spencer.it

EU DECLARATION OF CONFORMITY/ *DICHIARAZIONE DI CONFORMITA' UE*

Regulation/Regolamento UE 2017/745

The declaration is released under the sole responsibility of the manufacturer
La dichiarazione è rilasciata sotto la responsabilità esclusiva del fabbricante

Manufacturer/*Fabbricante:*	**Spencer Italia s.r.l.** Via Provinciale, 12 – 43038 Sala Baganza (PR) – Italy
Unique registration number/ *Numero di registrazione unico:*	IT-MF-000027507
Medical Device/*Dispositivo Medico:*	RES-Q-SPLINT SIZE L - VAC. SPL. WITH SEPAR. CHAMB. *RES-Q-SPLINT - STECCOBENDA DEPRESSIONE MIS.L*
Code /*Codice:*	QM22510A
BASIC UDI-DI /*UDI-DI di base:*	805771123STECCOBENDE4T
Lot/ *Lotto* SN/ *Matricola*	Not available before the production/ *Non disponibile prima della produzione*
Quantity/*Quantità:*	1
Risk class */Classe di rischio:* (Annex VIII/*Allegato VII)*	I
Conformity assessment procedure/ *Procedura valutazione conformità*	Not present/Non presente
Rule/*Regola:*	1

Spencer Italia S.r.l. declares under its sole responsibility that the above mentioned medical device is in compliance with the requirements of the Regulation 2017/745 and with the applicable regulations and common specifications.
Spencer Italia S.r.l. *dichiara sotto la sua sola responsabilità che il Dispositivo Medico sopra menzionato, è conforme ai requisiti del Regolamento 2017/745, alle norme e alle specifiche comuni applicabili.*

The list of applicable standards is reported in the Technical File.
La lista delle norme applicabili è riportata nel relativo Fascicolo Tecnico.

Sala Baganza (PR) - IT, 21/11/2022

First name and surname */Nome e cognome:*_____

Role/*Ruolo:* _____ Signature/*Firma:*_____

Person in whose name and on whose behalf this declaration of conformity has been signed/
Persona a nome e per conto della quale è stata firmata la presente Dichiarazione UE :

Antonio Ciardella
(Legal Representative */Legale Rappresentante)*

ECO AIR SPLINT KIT

Inflatable splints – Kit 6 sizes with bag

Air Splint splints are devices used to immobilise limbs in the event of suspected injuries or fractures of the limbs, to avoid additional strain during the pre-hospital phase.

Specific features
Low storage space required
Quick application thanks to the zip closure
Varying the inflation pressure is possible to increase or decrease the immobilization level of the limb
Color coded zip puller for quick size identification

Technical data	
Included sizes	Arm 37 cm
	Leg 40 cm
	Arm 64 cm
	Leg 67 cm
	Arm 75 cm
	Leg 85 cm
Material	PVC
Weight	1500 ± 50 g

Spencer Italia S.r.l. Sala Baganza (PR) Italia Tel. +39.0521.541111 Fax +39.0521.541222
spencer.it

QS24200A		
ECO AIR SPLINT - KIT 6 SIZES WITH BAG		
SET consisting of the following MD compliant with UE Reg. 2017/745		
QS24237 - AIR SPLINT - INFLATABLE SPLINT FOR ARM 37 CM	Reg. n. 103611	CND V0804
QS24240 - AIR SPLINT - INFLATABLE SPLINT FOR LEG 40 CM	Reg. n. 103636	CND V0804
QS24264 - AIR SPLINT - INFLATABLE SPLINT FOR ARM 64 CM	Reg. n. 103628	CND V0804
QS24267 - AIR SPLINT - INFLATABLE SPLINT FOR LEG 67 CM	Reg. n. 103639	CND V0804
QS24275 – AIR SPLINT - INFLATABLE SPLINT FOR ARM 75 CM	Reg. n. 103633	CND V0804
QS24285 - AIR SPLINT - INFLATABLE SPLINT FOR LEG 85 CM	Reg. n. 103644	CND V0804

Spencer Italia S.r.l. Sala Baganza (PR) Italia Tel. +39.0521.541111 Fax +39.0521.541222
spencer.it

JM80002

BLUE SPLINT KIT

Rigid splints with flexible internal structure

Available in five shapes and also adaptable to paediatric patients, these rigid splints are particularly resistant, easy to store and extremely versatile. The kit includes 5 rigid splints (leg, arm, forearm, wrist, elbow/ankle) with a storage bag. All splints can be reconfigured based on the patient's size or area to immobilize.
The kit include: transport bag for splints and an additional forearm splint.

CE

Easy to Clean

Easy to Store

SPLINT FOR LEG
Dimensions 580 x 450 mm
Weight 0,360 kg

SPLINT FOR ARM
Dimensions 590 x 280 mm
Weight 0,300 kg

SPLINT FOR FOREARM
Dimensions 390 x 300 mm
Weight 0,206 kg

SPLINT FOR WRIST
Dimensions 310 x 240 mm
Weight 0,145 kg

SPLINT FOR ELBOW/ANKLE
Dimensions 540 x 280 mm
Weight 0,273 kg

- Each splint includes a **self-adherent strips** to speed up the immobilization process.
- The kit can be used as an **armrest during intravenous infusions.**
- **Washable at 40°C** by removing the inner core.

- **Soft materials** ensure high comfort
- Materials **Neoprene, Al, Nylon**
- Dimensions **6200 x 310 mm**
- Weight **1,45 kg**

SPENCER

Patriot 836

Adjustable cervical collar

Size	Adults
Usage	Immobilization
Trauma	☑

See also

Patriot Baby 837

Description

Cervical collar adjustable to 4 different sizes. Designed to have in one article different possibilities of immobilization, it has been developed for the emergency medical use. Pre-molded chin support, locking clips, rear ventilation panel, enlarged trachea opening. The Patriot cervical collar is produced with high density polyethylene and foam padding; the flat one-piece design enables efficient storage where space is limited. X-ray lucent and easy to clean and disinfect.

CONTACT US

Via Langhirano, 270
43124 Fontanini (Parma) - Italy

+(39) 0521-648770

+(39) 0521-648780 +(39) 0521-390349

Email: info@meber.it

Patriot Baby 837

Adjustable cervical collar pediatric

Description

It has same technical features as adults collar. PATRIOT BABY is a pediatric cervical collar adjustable in 3 different sizes.

Main features

Size	Children
Usage	Immobilization
Trauma	☑
Pediatric	☑

CONTACT US

Via Langhirano, 270
43124 Fontanini (Parma) - Italy

+(39) 0521-648770

+(39) 0521-648780 +(39) 0521-390349

Email: info@meber.it

SED

Extrication/spine immobilization device

The SED extrication device is a first aid apparatus to be used for the extraction of a traumatised patient from a vehicle. It must be used after the application of the cervical collar to maintain immobilisation and head-torso alignment.

Specific features
Color coded belt system to make the application more intuitive and rapid
PVC coating for an easy sanitation
The separation of the rigid elements, allows high vertical rigidity and horizontal flexibility
Equipped with cushion for the nuchal area

Technical data	
Length	830 mm
Width	900 mm
Maximum thickness [1]	25 mm
Overall dimensions wrapped with bag (approx.)	850 x 250 x 120 mm
Belts length	74 ± 2 cm
Materials	PVC, Nylon, PP
Weight without bag	2,60 kg
Weight with bag	2,85 kg
Maximum load capacity	230 kg

1) at the hooks

Standard equipment
Transport bag

Class I MD compliant with UE Reg. 2017/745	
SED SPENCER EXTRICATION DEVICE	CE
SR00111B	
CND Classification	V0804
Registration number	102330

NATO stock n° 6515-15-149-8710

Rev.0 (30/11/2020)

UNCHECKED COPY – further revisions will be available on http://support.spencer.it

Spencer Italia S.r.l. Sala Baganza (PR) Italia Tel. +39.0521.541111 Fax +39.0521.541222

www.spencer.it

Declaration of compliancy CE

Manufacturer:	Spencer Italia Srl
Adress:	Strada Cavi 7 -43044 Collecchio Parma - ITALY
Product:	SED SPENCER EXTRICATION DEVICE
Code:	SR00111B

Classification (according to Council Directive 93/42/EEC, Annex IX): I

We hereby declare that the above mentioned products meet the provisions of 93/42/EEC Council Directive (MDD)

Application from the Annex VII (according to Council Directive 93/42/CEE)

Quality System Applied: ISO 9001-ISO 13485

Valid from date 10/14/2011

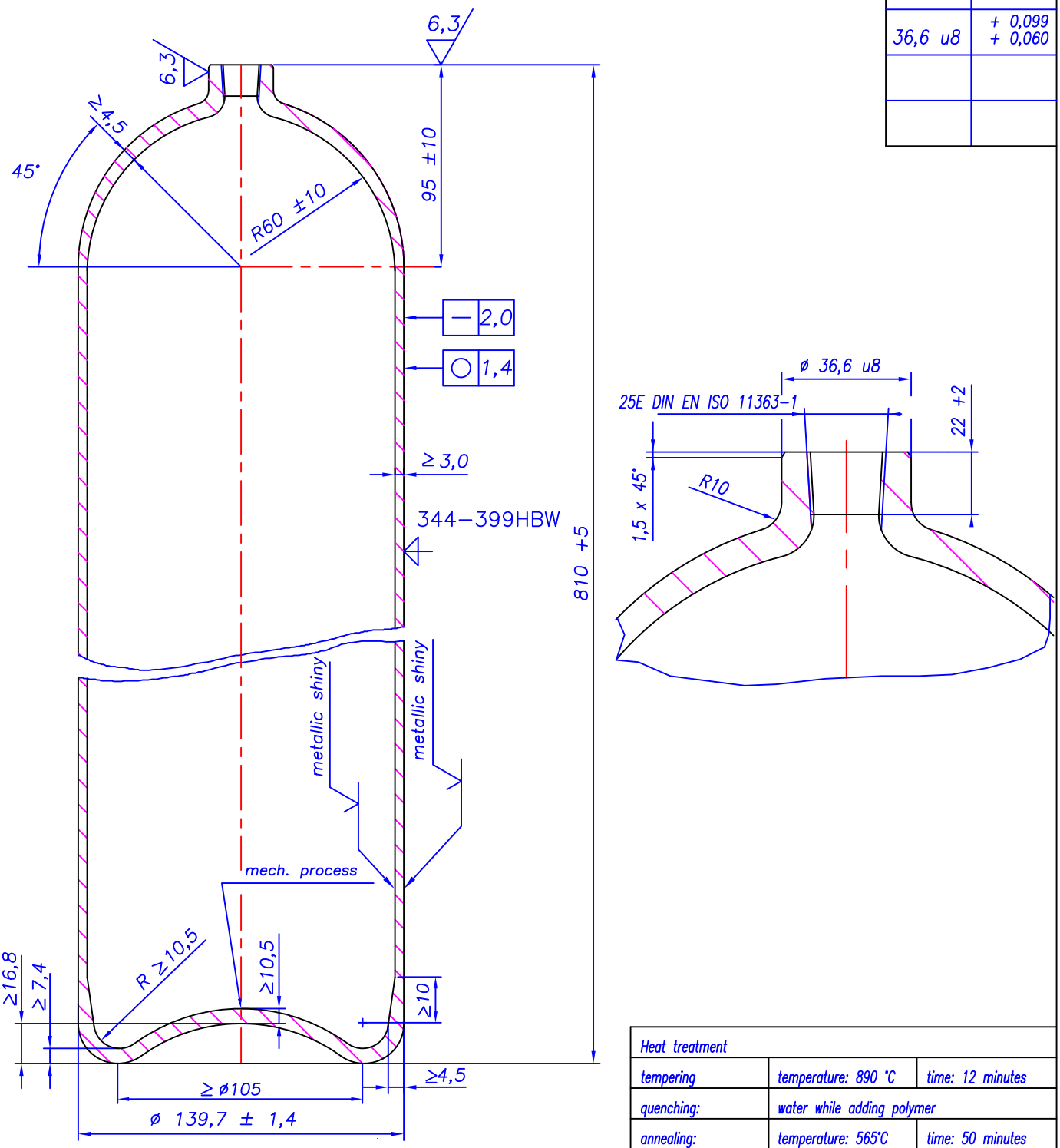
SPENCER ITALIA S.r.l.
Strada Cavi, 7
43044 COLLECCHIO (PR)
Tel. 0521.541111 | Fax 0521.541222

Signature an Position:_____

Luigi Cesare Pizzi Spadoni

Legal Representative

The Declaration of conformity issued for the lot or production number is filed in the Device Master Record and is available from our company files.



size	allowance
36,6 u8	+ 0,099 + 0,060

Heat treatment		
tempering	temperature: 890 °C	time: 12 minutes
quenching:	water while adding polymer	
annealing:	temperature: 565°C	time: 50 minutes

hydro pressure test Ph min. 30 s	ultrasonic test	Pb ≥ 480 bar	Py ≥ 401 bar	
Re 850 MPa	Rg 980 – 1099 MPa	A>max{12500/Rm;14}%		

on a scale of — weight appr.10,4kg

(material) 34CrMo4
R 139,7 x 3,1 (Mw.+20%) DIN EN 10297-1

	date	name
2016	09.11.	Seifert

(cyl body) **Flaschenkörper 10l**

(test pressure) 300 bar

regulation: DIN EN ISO 9809-1:2010
(RL2010/35/EU) 0090/EN49/12

(drawing number) **13 052 146 0 e**

ecs AG
eurocylinder systems

Gas Control Equipment

Intrebati

Pentru mai multe detalii despre acest produs, contactati echipa de vanzari din regiune.

MEDIREG® II

Cod produs: 3221

Whole medical range is available on gcehealthcare.com

NOUA GENERATIE DE REGULATOARE DE INALTA PRESIUNE MEDICALE

- Regulator cu debitul de iesire reglat constant sau cu debitmetru
- Manometru de presiune rotativ care permite intotdeauna o citire confortabila
- Design ergonomic
- Suprafata usor de curatat
- Compact si usor de folosit

735100000403 MediReg II leaflet RO

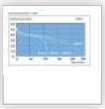
DATE TEHNICE

Gaz:	O_2, Aer, N_2O, CO_2, O_2/N_2O, Xe, Ar
Presiune intrare:	Pana la300 bar
Presiune iesire:	4 bar
Racord intrare:	conform standardelor nationale
Pressure outlet:	DIN, AFNOR, SS, CZ etc.
Material corp:	Alama nichelata
Buton control:	Poliamida
Garnituri O:	EPDM
Filtru:	Bronz sinterizat
Protectie manometru:	TPE (elastomer termoplastic)
Certificare regulatoare:	Conform cu Medical Devices Directive 93/42/EEC Conform cu EN 10524-1 (Regulatoare de presiune pentru utilizarea gazelor medicale) Conform cu Standard EN 1789:2000 (Vehicule medicale si echipamentele lor – Ambulante rutiere)
Clasificare:	Clasa IIb
Producător:	GCE, s.r.o, Žižkova 381, 583 81 Chotěboř, CZ

Informatii tehnice

Sus

Descarcati informatiile tehnice




Produse similare

Sus

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10401-2017-CE-CZS-NA-PS Rev. 5.0	PRJC-189266-2009-PRC-CZE	27 May 2024

This is to certify that the quality system of:

GCE s.r.o.

Žižkova 381,583 01 Chotěboř, Czech Republic

For design, production and final product inspection/testing of:

MEDICAL DEVICES FOR USE WITH MEDICAL GASES

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 15 September 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	**Description**	**Issue Date**
0.0	Supersedes DNV GL (NB0434) certificate No. 73547-2010-CE-CZS-NA 7.0 following transfer of notified body function to DNV Nemko Presafe AS (NB2460)	2017-11-01
1.0	Correction pagination	2018-07-11
2.0	Scope extension – added new variants of Pressure regulators integrated with cylinder valves - MediVital A and MediVital E	2018-08-22
3.0	Re-certification	2020-03-30
4.0	Scope Extension – added new models in Bold High Pressure Regulators, model MEDITEC Flow-metering devices, model MediFlowTec As listed in the List of Models dated 11-09-2020	2020-09-11
5.0	**Removing models – Gas Switch, Gas Alarm C44, Gas Alarm G4, Gas Alarm MC7701, Gas Alarm Touch, as per** List of Models dated 14-09-2020	**2020-09-15**

Products covered by this Certificate:

Product Description	Product Name	Class
Medical devices for use with Medical Gases	Flow-metering devices (Ball flow meters, Flow selectors) Humidifiers Low pressure hoses Low pressure regulators Terminal Unit (for Anesthetic Gas Scavenging System) Suction equipment (Suction ejectors, Vacuum regulators) Demand Valve Gas Saver	IIa
Medical devices for use with Medical Gases	Pressure regulators integrated with cylinder valves Cylinder valves High Pressure Regulators Terminal Unit Ambulance Panel Central gas supply system Resuscitator Adjustable regulators	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
GCE s.r.o.	Žižkova 381, 583 01 Chotěboř, Czech Republic

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

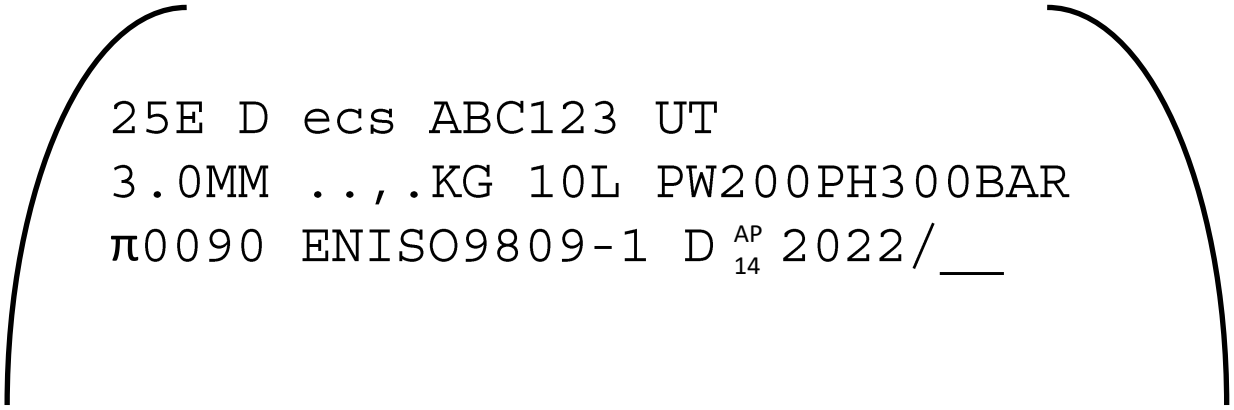
- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

Front:



Back:

	17.03.2022	**Marking**
	Mund	REV 10L 57032
		Revision 0

eurocylinder systems AG • Auenstrasse 21 • D-99510 Apolda

Konformitätserklärung

Conformity declaration / Déclaration de conformité / Dichiarazione di conformità

Folgende Stahlflaschen wurden in Übereinstimmung mit der Richtlinie 2010/35/EU hergestellt.

The following steel cylinders were manufactured acc. directive 2010/35/EU.
Les bouteilles en acier suivantes ont été fabriquées en conformité avec la directive 2010/35/UE. Le bombole sono state prodotte secondo la direttiva 2010/35/UE.

Auftragsnummer: Order no / M. de commande / Ordine no:	23/57734/2
Kunde: Customer / Cliente / Client:	Rév Gas Industries Ltd.
Stückzahl: Quantity / Quantité / Quantità:	200
Fassungsraum: Volume / Volume / Volume:	10 l
Prüfdruck: Test pressure / Pression d'épreuve / Pressione Prova:	300 bar
Herstellernummern: Manufacturer's no. / No. di série / Numero de serie:	MTO013-MTO189, MTP001-MTP025 (excl.MTO099, MTO111)
Kundennummern: Customer no / No. di cliente / Numero client:	-
Vorschrift: Rule / Règlementation / Regola:	EN ISO 9809 - 1 : 2010
Zulassungsnummer: Approval no / Numéro de agrément / Approvazione no:	0090/EN49/12
Konformitätszeichen: Conformity mark / No de conformité / Conformità no:	π
Kennnummer: Reference no / Numéro d'identification / Riferimento no:	0090

Apolda, 10.01.2023

i.A./pp. Förtsch
(ecs AG)

F10 Ausgabe 2 / 01.06.2022

eurocylinder systems AG
Auenstrasse 21, D-99510 Apolda
Tel: +49 (0) 3644 621 - 0
Fax: +49 (0) 3644 621 - 203

Vorstand:
Michael Dathe
Vorsitzender des Aufsichtsrates:
Daniel Spannagel

Sitz Apolda
Amtsgericht Jena: HRB 501 803
UST-Id-Nr.: DE150089541
St.-Nr.: 162/100/00856

UniCredit Bank AG
BLZ 820 200 87, Kto. 404 24 25
SWIFT-BIC: HYVEDEMM098
IBAN: DE04 8202 0087 0004 0424 25

Deutsche Bank AG
BLZ 820 700 00, Kto. 399 400 100
SWIFT-BIC: DEUTDE8E
IBAN: DE25 8207 0000 0399 4001 00

Landesbank Baden-Württemberg
BLZ 600 501 01
SWIFT-BIC: SOLADEST600
IBAN: DE39 6005 0101 0004 6603 98

Die Kennzeichnung mit P15Y durch die eurocylinder systems AG erfolgt im Auftrag nach den Vorgaben des Kunden. Die eurocylinder systems AG überprüft nicht, ob die rechtlichen Voraussetzungen für eine Kennzeichnung P15Y vorliegen. Es ist die ausschließliche Pflicht des Kunden und allen folgenden Eigentümern zu überprüfen, dass die einschlägigen Vorschriften der ADR/RID P200 eingehalten werden. Die eurocylinder systems AG ist nicht verantwortlich sicherzustellen, ob der Kunde und alle folgenden Eigentümer zu einer Kennzeichnung mit P15Y autorisiert sind oder ob die Voraussetzungen für die Kennzeichnung P15Y vorliegen.

The labeling with P15Y by eurocylinder systems AG is carried out in the order according to the customer's specifications. Eurocylinder systems AG does not check whether the legal requirements for a P15Y label are met. It is the sole responsibility of the customer and any subsequent owners to check that the relevant provisions of ADR/RID P200 are complied with. Eurocylinder systems AG is not responsible for ensuring whether the customer and all subsequent owners are authorized to label with P15Y or whether the requirements for labeling P15Y are met.

Le marquage avec P15Y par eurocylinder systems AG est effectué à la commande selon les spécifications du client. eurocylinder systems AG ne vérifie pas si les exigences légales pour une étiquette P15Y sont remplies. Il est de la seule responsabilité du client et des éventuels propriétaires ultérieurs de vérifier que les dispositions pertinentes de l'ADR/RID P200 sont respectées. eurocylinder systems AG n'est pas responsable de s'assurer que le client et tous les propriétaires ultérieurs sont autorisés à étiqueter avec P15Y ou si les exigences d'étiquetage P15Y sont remplies.

La marcatura con P15Y da parte di eurocylinder systems AG viene effettuata per conto del cliente secondo le specifiche del cliente. Eurocylinder systems AG non verifica se i requisiti legali per una marcatura P15Y sono soddisfatti. È dovere esclusivo del cliente e di tutti i successivi proprietari verificare che siano rispettate le disposizioni pertinenti dell'ADR/RID P200. Eurocylinder systems AG non è responsabile di garantire se il cliente e tutti i successivi proprietari sono autorizzati a etichettare P15Y o se i requisiti per la marcatura P15Y sono soddisfatti.

eurocylinder systems AG
Auenstrasse 21, D-99510 Apolda
Tel: +49 (0) 3644 621 - 0
Fax: +49 (0) 3644 621 - 203

Vorstand:
Michael Dathe
Vorsitzender des Aufsichtsrates:
Daniel Spannagel

Sitz Apolda
Amtsgericht Jena: HRB 501 803
UST-Id-Nr.: DE150089541
St.-Nr.: 162/100/00856

UniCredit Bank AG
BLZ 820 200 87, Kto. 404 24 25
SWIFT-BIC: HYVEDEMM098
IBAN: DE04 8202 0087 0004 0424 25

Deutsche Bank AG
BLZ 820 700 00, Kto. 399 400 100
SWIFT-BIC: DEUTDE8E
IBAN: DE25 8207 0000 0399 4001 00

Landesbank Baden-Württemberg
BLZ 600 501 01
SWIFT-BIC: SOLADEST600
IBAN: DE39 6005 0101 0004 6603 98

EU DECLARATION OF CONFORMITY

Certificate Number:	*ZP 03-006 High Pressure Regulators_09-07*
Manufacturers Name:	GCE, s.r.o.
Manufacturers Address:	Žižkova 381, 583 01 Chotěboř, Czech Republic
SRN (Single Registration Number):	003172 RZPRO
Product Group:	*High Pressure Regulators*
Name of the Device (s):	**MEDIREG II**
Product code:	7085
Risk Classification:	IIb
GMDN code:	43438
Other used standards:	**EN ISO 10524-1:2018**
Notified Body name:	DNV Product Assurance AS
Notified Body Address:	Veritasveien 3, N-1363 Høvik, Norway
Notified Body Identification number:	2460
EC Certificate Number:	10401-2017-CE-CZS-NA-PS

Conformity assessment route:

This declaration of conformity is issued under the sole responsibility of GCE, s.r.o. We hereby declare that he medical device(s) specified above meet the provision of the Regulation MDD 93/42/EEC for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by DNV Product Assurance AS.

The product is in accordance with Annex II (excluding section 4) of the MDD 93/42/EEC and is safe for declared purpose of use under standard conditions. Any modification to the product, not authorized by us, will invalidate this declaration.

All supporting documentation is retained at the premises of the manufacturer.

Signature: Place and date (dd.mm.yyyy) of issue:

Ing. Tereza Šnapková
Digitálně podepsal Ing. Tereza Šnapková
Datum: 2021.05.28 13:44:08 +02'00'

....Chotěboř

Tereza Šnapková

Regulatory Specialist, On behalf of Tomáš Janeček, managing director.

Note: List of variants is in attachment of this docoment.

BEPD Betriebseigener Prüfdienst der eurocylinder systems AG
Inhouse inspection service of eurocylinder systems AG
Service de contrôle interne de eurocylinder systems AG

ecs AG eurocylinder systems

eurocylinder systems AG, Auenstraße 21, D-99510 Apolda ✆ + 49 (0) 36 44 - 62 1-0 + 49 (0) 36 44 - 62 12 03 www.eurocylinders.com

ZERTIFIKAT

CERTIFICATE / CERTIFICAT

über die Konformität der Herstellung gemäß RL 2010/35/EU, ADR/RID 2021, 1.8.7.4
of conformity of manufacture acc. to dir. 2010/35/EU ADR/RID 2021, 1.8.7.4
de conformité de la fabrication selon la dir. 2010/35/EU ADR/RID 2021, 1.8.7.4

Zertifikat-Nr., Certificate No., N° de certificate **: Π / LWD / 1014 / 2022**

Name und Anschrift des Herstellers / Fertigungsstätte: **eurocylinder systems AG**
Name and address of manufacturer/place of manufacture **Auenstraße 21**
Nom et adresse du fabricant / Lieu de fabrication: **99510 Apolda**

Hiermit wird bescheinigt, dass die ortsbeweglichen Druckgeräte die Anforderungen der RL 2010/35/EU und des ADR/RID 2021 erfüllen. Die Druckgeräte entsprechen den zur Baumusterzulassung eingereichten Unterlagen und sind mit dem abgebildeten Zeichen gekennzeichnet. This is to certify, that the transportable pressure equipment listed below meet the requirements of the Transportable Pressure Equipment Directive 2010/35/EU and the ADR/RID 2021. The pressure equipment complies the documents submitted for type approval and is marked with the following symbol. Nous certifions ci-joint que les appareils à pression mobiles sur différents lieux répondent aux exigences conformément à la directive 2010/35/EU et à la directive ADR/RID 2021. Les appareils à pression répondent aux contrôles des prototypes CE et sont caractérisés par les sigles représentés.

π 0090

Die Druckgeräte sind mit einem Ventil mit PI-Kennzeichnung auszurüsten.
The pressure devices are tob e fitted with a valve with PI-marking.
Les appareils à pression sont equips d´une vanne avec le caractére PI.

Geprüft nach Richtlinie 2010/35/EU, ADR/RID 2021: Tested under Directive 2010/35/EU, ADR/RID 2021 : Contrôlé selon la directive 2010/35/EU, ADR/RID 2021:	**Erstmalige Prüfung** Initial inspection and test Contrôle et épreuves initiaux
Prüfbericht-Nr.: Test report No.: Nr. de rapport de contrôle:	**LWD / 2022**
Herstell-Nr.: Manufacturer`s serial No.: Nr. du fabricant:	**LWD001 – LWD194**
Beschreibung des Druckgerätes: Description of pressure equipment: Description de l'appareil à pression:	**Nahtlose Stahlflaschen Familie EN 49 / 10,0 l** Seamless steel cylinder ...., family / l Surface en acier sans raccords ...., Famille / l
Norm: Standard: Standard:	**EN ISO 9809 – 1 : 2010**
Zertifikat-Nr. des Baumusters: Type certificate No.: Nr. de certificat du prototype:	**0090 / EN49 / 12**

Tropschug

Apolda, 22.07.2022
(Ort, Datum) (place, date)
Betriebseigener Prüfdienst der eurocylinder systems AG
Inhouse inspection service of eurocylinder systems AG,
Service de contrôle interne de eurocylinder systems AG

F030_01.1.1 / Ausgabe 6/08.03.2022

ecs eurocylinder systems	BEPD-Qualitätssicherungssystem **Prüfbericht** Inspection Report/rapport du test	Ausgabe: 3/02.01.2020	F007_01.1.1 Seite 1/2

Prüfberichts-nr.
Report-nr.
Rapport-n° L W D/2022

Zertifikat-nr. π / LWD / 1014 / 2022
Certficate-nr. CE/ / /
N° de certificat

Glühlos/batch-nr./lot / Jahr/year/an

Volumen 10,0 dm³
Volume dm³
Volume dm³

Zulassungs-Nr. 0090/EN49/12
Approved-nr.
N° d´homologation

Prüflosgröße 202 Stück
Inspection lot size pieces
Volume du lot de contrôle pieces

Prüfdruck 300 bar
Test pressure bar
Pression d´épreuve bar

Zeichnungs-Nr. 130521460
Drawing-nr.
Plan-n°

Werkstoff 34CrMo4
Material
Matière

Abmessung 139.7 × 3.1
Dimensions
Dimensions

Gütepass 14 / 2022
Material certificate
Certificat matière

Chargen-Nr. 209965
Charge-nr.
Charge-n°

Chargen-Kennzeichnung grau
Charge identification
Identification de la charge

1. Angaben zur Wärmebehandlung
Information to the heat treatment
Informations concernant le traitment thermique

Vergüten/Quenching and tempering/Trempe et revenu

Austenitisieren 880 °C 10 min
Austenising
Austénisation

Badtemperatur 25 - 38 °C
Bath temperature
Température du bain

Polymerkonzentratior 5,5 % Kontrollwert 5,5 %
Polymer concentration % Check value %
Polymére concentration % Valeur contrôle %

Anlassen 565 °C 50 min
Tempering
Revenu

Arbeitsvorbereiter
Operations sheduler
Préparateur du travail 20.07.22
Unterschrift signing signature / Datum date date

2. Bestätigung über die Einhaltung der technologischen Parameter
Compliance with technical parameters
Conformité des caractéristique techniques

Härter
Hardener
Trempeur 19.07.2022
Unterschrift signing signature / Datum date date

3. Ergebnis der Werkstoffprüfung (einschl. Berst-/Härteprüfung)
Result of the material test (inclusive bursting test/ hardness test)
Résultat du contrôle matière (incluse essai de rupture/test de dureté)

Vorgabewerte **erreicht / nicht erreicht**
Allowed values are / ~~are not reached~~
Valeurs autorisées sont / ~~ne sont pas atteintes~~

BEPD-WP
Inhouse inspection service
Service de contrôle interne 22. Juli 2022
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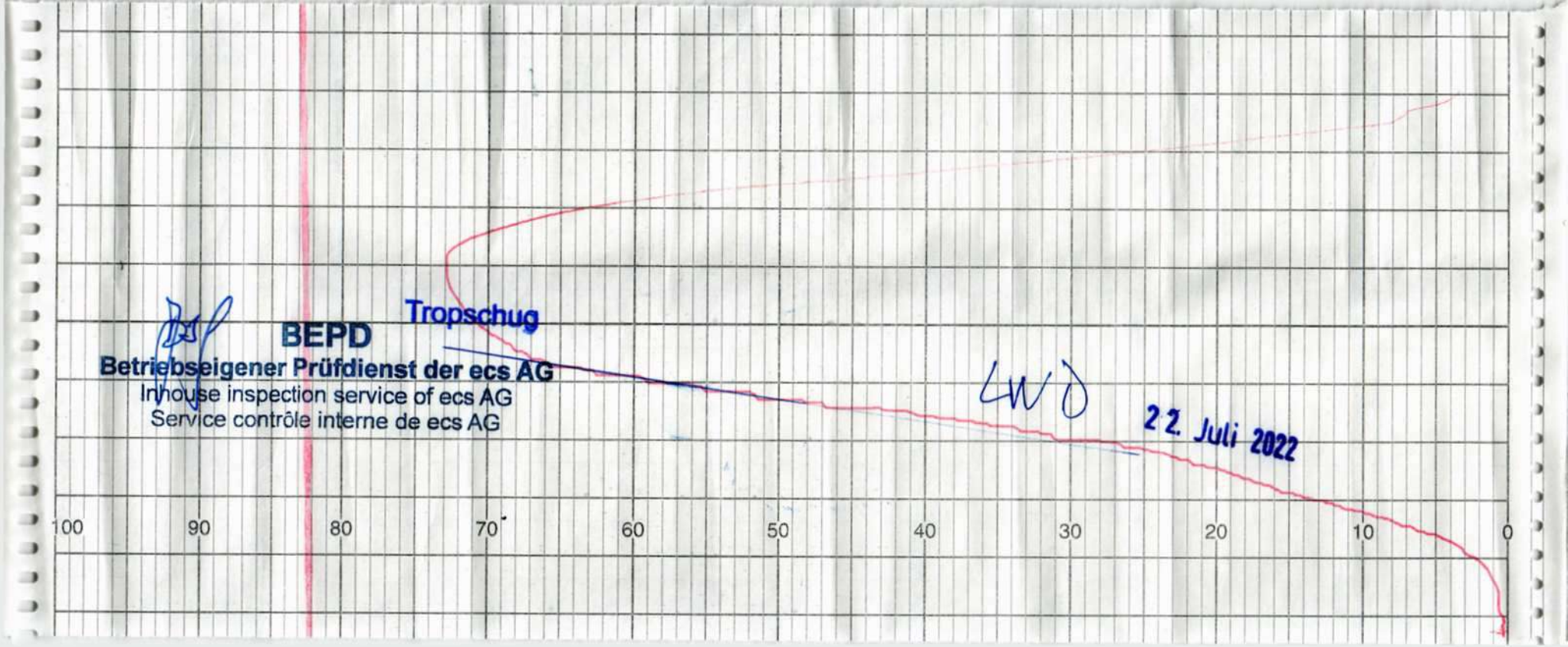

Tropschug
BEPD
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG
22. Juli 2022
100
90
80
70
60
50
40
30
20
10
0

ecs eurocylinder systems	BEPD-Qualitätssicherungssystem **Werkstoffprüfbericht**	Ausgabe: 2/26.09.2014	F008_01.1.0

Werkstoffprüfbericht/Material Test Report/Procés-verbal de contrôle matiére

Dieser Prüfbericht gehört zur Glühlos - Nr. LWD/2022 **und dem dazugehörigen Kontrollbericht.**
This test report is part of heat treatment batch- nr. ____ and the corresponding inspection report.
Le présent procés-verbal fait partie de no. de lot de traitement thermique____ et du procés-verbal de contrôle.

Volumen/Volume/Volume: 10,0 dm³ **Zulassung**/Approval/Permission: 0090/EN49/12

Ergebnisse der Werkstoffprüfung/Results of the material test/ Résultat du contrôle matiére:
nach DIN EN ISO 9809 – 1 : 2010 / nach DIN EN ISO 9809 – 2 : 2010

Zugversuch Tensile test Essai de traction	Abmessungen Dimensions Dimensions nach DIN EN ISO 6892 – 1 : 2009 B nach DIN EN ISO 6892 – 2 : 2011 B				Kraft Force Force N		Δl mm	Härte an Prüfflasche Hardness of the test cylinder Dureté de la bouteille d' essai nach DIN EN ISO 6506–1:2015
Prüftemp. Test temp. Temp. d'epreuve [°C]	Breite Width Largeur [mm]	Dicke Thickness Epaisseur [mm]	Fläche Area Surface [mm²]	Messlänge Measuring length Longueur de mesure [mm]	Streck-grenze Yield point Limite apparente d'elasticité [N/mm²]	Zugfestig-keit Tensile strength Résistance a' la traction [N/mm²]	Dehnung Elongation Allongement [%]	[HB 30]
20	20,0	3,6	72,0	50	670 931	730 1014	8,0 16,0	375

Kerbschlagbiegeversuch/ Impact test/ Essai de résilience nach DIN EN ISO 148 – 1 : 2011							Faltversuch Bend test/ Essai de pliage nach DIN EN ISO 7438 : 2012 (D= 6 s ; 180°) 4 × o. A.
Proben-Nr. Sample no. Numero d'echantillon	Breite Width Largeur [mm]	Höhe Height Hauteur [mm]	Fläche Area Surface [cm²]	Arbeit Work Travail [J]	Kerbschlag-zähigkeit Impact value Résilience [J/ cm²]	Mittelwert Mean value Valeur moyenne [J/ cm²]	
LWD.1	3,5	8,0	0,28	33,0	118	110	Hals – und Bodenprüfung Neck and bottom test Contrôle de col et fond
LWD.2	3,5	8,0	0,28	29,5	105		----------
LWD.3	3,5	8,0	0,28	30,0	107		
							Berstprüfung Bursting test/Essai de rupture
							545 bar

Probelage: Position of the sample/ Position de flexion	Längs / longitudinal
Prüftemperatur: Test temperature/ Temperature d'epreuve	-50°C
Kerbform: Form of the notch/ Form de l'entaille	V nach DIN EN ISO 148 – 1 : 2011
Kerbrichtung: Direction of the notch/ Direction de l'entaille	Senkrecht / perpendicular
Prüfmaschine : Test machine/ Machine d'essai	PS 30

Prüfer/ tester/ contrôleur
BEPD-WP
Apolda, 22.07.2022

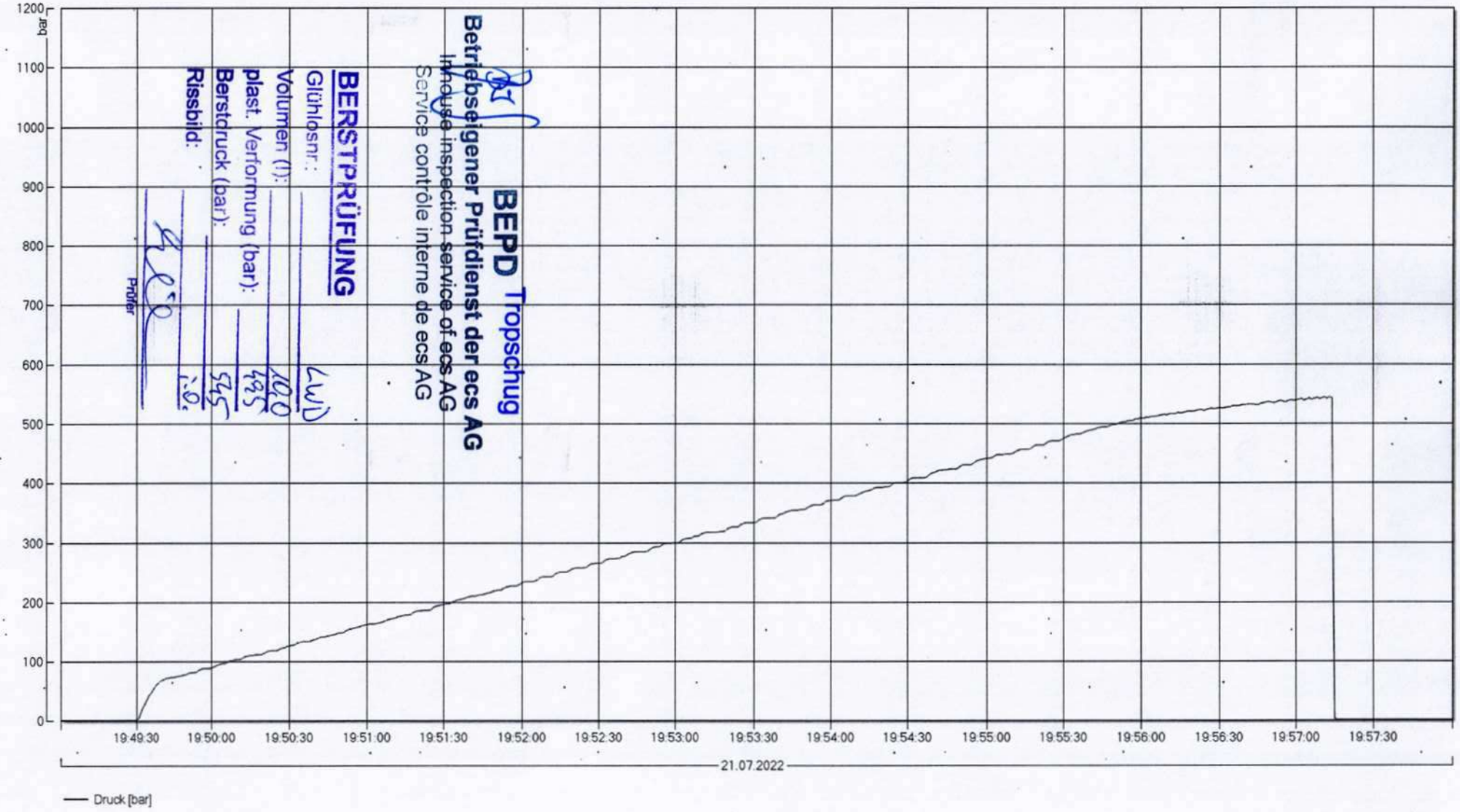
Leitung BEPD
direction inhouse inspection service/service de contrôle interne
Unterschrift signing signature/ Datum date date

BEPD Tropschug
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG

Messwerte / Trend
Gerätename: Berstpruefung (Seriennummer J500F904428)
Zeitbereich: 21.07.2022 19:49:00 bis 21.07.2022 19:58:00

22.07.2022 10:19:42

Vorlage: 2022-07
Glühlos LWD
Manometer Nr. 082502279



BEPD Tropschug
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG

BERSTPRÜFUNG
Glühlosnr: LWD
Volumen (l): 200
plast. Verformung (bar): 495
Berstdruck (bar): 545
Rissbild: i.O.
Prüfer

EUROCYLINDER SYSTEMS AG

Parameter :lwd-10-0 24.02.13 - 03:03

Chargen-Nr.	
SB-Nr.	LVD
Volumen	10,0
Fl.-Beh.-Typ	
Schicht	3
Anlagenfahrer	Lobenstein
Prüfmethode	HB 30
Härteminimum	344
Härtemaximum	399

Meßwerte/Flasche	1
Meßwerte gesamt	200
Losanzahl	200
Anzahl Klassen	5
Anzahl Härteverlauf	100

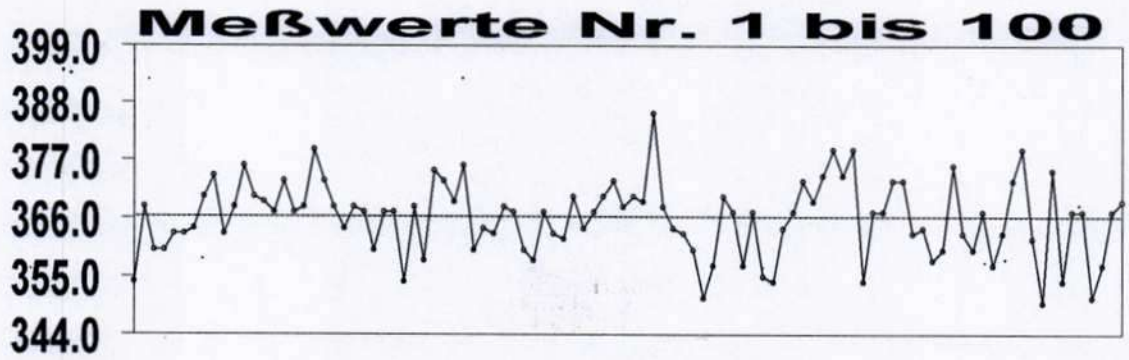
Statistikwerte :[HB 30]

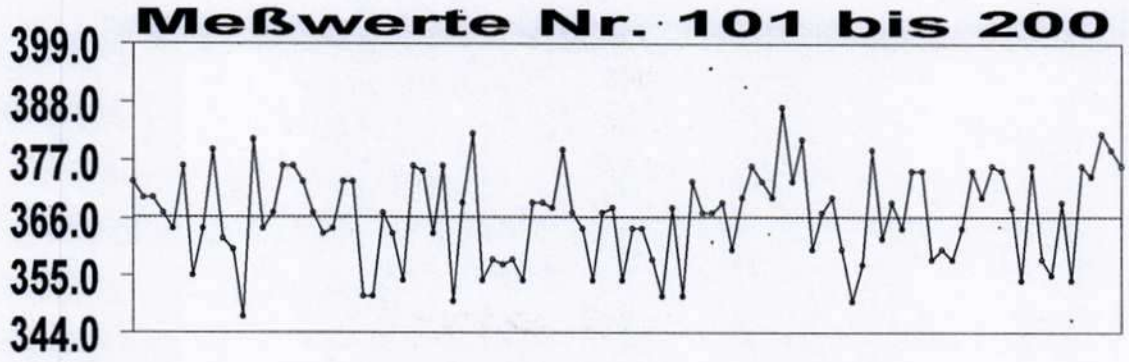
Gesamtanzahl	:	200
Anzahl in Grenzen	:	200
Anzahl zu weich	:	0
Anzahl zu hart	:	0
Anzahl ST	:	200
kleinster Wert	:	347.0
größter Wert	:	387.0
Xquer	:	366.240
Standardabweichung		7.991

Histogramm :

		0.00 %
399.0		0.00 %
388.0		7.00 %
377.0		50.50 %
366.0		31.50 %
355.0		11.00 %
344.0		0.00 %

Härteverlauf :[HB 30]





BEPD Tropschug
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG

Datum: 21 Juli 2022 **Unterschrift:** _____

KARL DEUTSCH

Gesamtprotokoll

STFL ECHOGRAPH 1155 [55281]

EUROCYLINDER SYSTEMS

Datum des Ausdrucks: 21.07.2022 14:39:31

Prüflose-Nr.	LWD
Abmessung	139,7x3,0
Werkstoff	34CrMo4
Charge	209965
Prüfspezifikation	ENISO 9809-1

letztes Pruefdatum: 21.07.2022 14:38:51

Pruefdaten:

Programm: 140-10-130521460.dat(0.TE)

Parameter-Auswahl:

USEL: 140x3,0.usel(0.TE)

DAV: 139,7x10,0.dav(0.TE)

Ultraschall

Ultraschall1

Ultraschall2

Ultraschall3

Ultraschall4

Ultraschall5

Statistik:

	Stueck	%	Laenge [m]	%
Gesamt:	194	100.00	1107.06	100.00
Gut:	194	100.00	1107.06	100.00
auffällig/Wiederholungsprü.	0	0.00	0.00	0.00
unsichere Kopplung	0	0.00	0.00	0.00

BEPD Tropschug
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG

Unterschrift: i.A. Kn.

[redacted]	BEPD-Qualitätssicherungssystem Wasserdruckprüfung	Ausgabe: 1/01.05.2014	F011_01.1.1

Bescheinigung über die Durchführung der Wasserdruckprüfung

Certificate about the realisation of the hydraulic test
Certificat sur la mise en œuvre de l'examen de pression hydraulique

Los / Batch / Lot: ..LWD.....

Prüfdruck / Test pressure / Pression d'essai: ..300..... bar (Manometer Nr.: 121502075)

Stückzahl / Piece no. / No. de pièces: ..200... gut / good / bonnes: ..199 schlecht / defect / rebut: ..1....

Die Stahlflaschen wurden mit dem Prüfdruck beaufschlagt. Bei den für gut befundenen Stahlflaschen zeigten sich keine Undichtigkeiten und keine bleibenden Verformungen.
The cylinders have been impinged with the test pressure. In case of the as good considered steel cylinders were no leakages and permanent deformations. / Les bouteilles en acier ont été soumises à la pression d'essai. Les bouteilles en acier considérées comme bonnes ne présentent aucune fuite ni aucune déformation permanente.

Volumenermittlung / Determination of volume / Détermination du volume

Bei 10 % der Stahlflaschen des Loses wurde das Volumen ermittelt.
The volume of 10 % of the steel cylinders from the lot was determined./ Le volume de 10 % des bouteilles en acier a été déterminé.

Volumen (min.)/ Volume (min.) : 10.0... l

Lfd.Nr./ Serial no./No.cour.	Volumen(l)/ Volume(l)	Lfd.Nr./ Serial no./No.cour.	Volumen(l)/ Volume(l)
01	10,2	11	10,1
02	10,2	12	10,2
03	10,2	13	10,2
04	10,2	14	10,2
05	10,1	15	10,2
06	10,2	16	10,2
07	10,2	17	10,1
08	10,2	18	10,2
09	10,2	19	10,3
10	10,1	20	10,2

Der Prüfer bestätigt die Prüfung und Einhaltung der Anforderungen nach Kontrollvorschrift KV011_01 bezüglich Sichtprüfung der Außenseite, Innenbesichtigung, Gewindeprüfung, Maßkontrolle und Fußringsitz. / The tester confirm the check and the compliance in terms of the requirements to test direction KV011_01 regarding external visual testing, internal visual testing, thread test, dimensional inspection and base ring fit. L'inspecteur confirme la vérification et la conformité avec les exigences de contrôle KV011_01 concernant l'inspection visuelle à l'extérieur et à l'intérieur, contrôle de taraudage, contrôle dimensionnel et que la bague de pièd convient.

BEPD-WPS/US
inhouse inspection service
service de contrôle interne : A. Wich 21.07.22
Unterschrift signing signature / Datum date date

Leitung BEPD
direction inhouse inspection service
service de contrôle interne
Unterschrift signing signature / Datum date date

BEPD Tropschug
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG

SB-NR.: LWD ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :1

Auftrag/order/commande: 22-56943-2

Kunde/customer/client : GPG-GmbH

EUROCYLINDER SYSTEMS AG

Volumen/volume/volume V/l: 10 l
Prüfdruck/test pressure/pression d epreuve: 300 bar
Gasart/kind of gas/sorte du gaz: Verd. Gas
Fülldruck/filling pressure/pression d service: 200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees: 0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWD001	11.4	405			
LWD002	11.4	406			
LWD003	11.4	407			
LWD004	11.4	408			
LWD005	11.4	409			
LWD006	11.4	410			
LWD007	11.4	411			
LWD008	11.4	412			
LWD009	11.4	413			
LWD010	11.4	414			
LWD011	11.3	415			
LWD012	11.4	416			
LWD013	11.4	417			
LWD014	11.4	418			
LWD015	11.4	419			
LWD016	11.3	420			
LWD017	11.3	421			
LWD018	11.3	422			
LWD019	11.3	423			
LWD020	11.3	424			
LWD021	11.3	425			
LWD022	11.3	426			
LWD023	11.3	427			
LWD024	11.3	428			
LWD025	11.3	429			
LWD026	11.3	430			
LWD027	11.3	431			
LWD028	11.3	432			
LWD029	11.3	433			
LWD030	11.3	434			
LWD031	11.4	435			
LWD032	11.4	436			
LWD033	11.4	437			
LWD034	11.3	438			
LWD035	11.3	439			
LWD036	11.4	440			
LWD037	11.4	441			
LWD038	11.4	442			
LWD039	11.4	443			
LWD040	11.4	444			

40 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 500

APOLDA, 21.07.2022

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SB-NR.: LWD ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :2

Auftrag/order/commande: 22-56943-2

Kunde/customer/client : GPG-GmbH

EUROCYLINDER SYSTEMS

Volumen/volume/volume V/l:	10 l
Prüfdruck/test pressure/pression d epreuve:	300 bar
Gasart/kind of gas/sorte du gaz:	Verd. Gas
Fülldruck/filling pressure/pression d service:	200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees:	0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWD041	11.4	445			
LWD042	11.4	446			
LWD043	11.3	447			
LWD044	11.3	448			
LWD045	11.4	449			
LWD046	11.4	450			
LWD047	11.3	451			
LWD048	11.4	452			
LWD049	11.3	453			
LWD050	11.3	454			
LWD051	11.3	455			
LWD052	11.3	456			
LWD053	11.4	457			
LWD054	11.3	458			
LWD055	11.4	459			
LWD056	11.3	460			
LWD057	11.4	461			
LWD058	11.4	462			
LWD059	11.4	463			
LWD060	11.3	464			
LWD061	11.4	465			
LWD062	11.4	466			
LWD063	11.4	467			
LWD064	11.4	468			
LWD065	11.4	469			
LWD066	11.4	470			
LWD067	11.4	471			
LWD068	11.3	472			
LWD069	11.4	473			
LWD070	11.4	474			
LWD071	11.4	475			
LWD072	11.4	476			
LWD073	11.4	477			
LWD074	11.4	478			
LWD075	11.4	479			
LWD076	11.4	480			
LWD077	11.4	481			
LWD078	11.4	482			
LWD079	11.4	483			
LWD080	11.4	484			

40 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 500

APOLDA, 21.07.2022

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SB-NR.: LWD ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL

EUROCYLINDER SYSTEMS

Auftrag/order/commande: 22-56943-2

Kunde/customer/client : GPG-GmbH

Volumen/volume/volume V/l: 10 l
Prüfdruck/test pressure/pression d epreuve: 300 bar
Gasart/kind of gas/sorte du gaz: Verd. Gas
Fülldruck/filling pressure/pression d service: 200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees: 0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWD081	11.4	485			
LWD082	11.4	486			
LWD083	11.3	487			
LWD084	11.4	488			
LWD085	11.4	489			
LWD086	11.3	490			
LWD087	11.3	491			
LWD088	11.4	492			
LWD089	11.4	493			
LWD090	11.3	494			
LWD091	11.3	495			
LWD092	11.3	496			
LWD093	11.3	497			
LWD094	11.4	498			
LWD095	11.4	499			
LWD096	11.3	500			
LWD097	11.3	501			
LWD098	11.3	502			
LWD099	11.3	503			
LWD100	11.3	504			
LWD101	11.3	505			
LWD102	11.3	506			
LWD103	11.3	507			
LWD104	11.3	508			
LWD105	11.3	509			
LWD106	11.3	510			
LWD107	11.3	511			
LWD108	11.3	512			
LWD109	11.3	513			
LWD110	11.4	514			
LWD111	11.4	515			
LWD112	11.4	516			
LWD113	11.3	517			
LWD114	11.3	518			
LWD115	11.4	519			
LWD116	11.4	520			
LWD117	11.4	521			
LWD118	11.4	522			
LWD119	11.4	523			
LWD120	11.3	524			

40 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 500

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SB-NR.: LWD ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :4

Auftrag/order/commande: 22-56943-2

Kunde/customer/client : GPG-GmbH

Volumen/volume/volume V/l: 10 l
Prüfdruck/test pressure/pression d epreuve: 300 bar
Gasart/kind of gas/sorte du gaz: Verd. Gas
Fülldruck/filling pressure/pression d service: 200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees: 0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWD121	11.3	525			
LWD122	11.3	526			
LWD123	11.4	527			

3 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 500

APOLDA, 21.07.2022

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SB-NR.: LWD ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :1

Auftrag/order/commande: 22-56943-1

Kunde/customer/client : GPG-GmbH

EUROCYLINDER SYSTEMS

Volumen/volume/volume V/l:	10 l
Prüfdruck/test pressure/pression d epreuve:	300 bar
Gasart/kind of gas/sorte du gaz:	Verd. Gas
Fülldruck/filling pressure/pression d service:	200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees:	0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWD124	11.4	501			
LWD125	11.3	502			
LWD126	11.3	503			
LWD127	11.3	504			
LWD128	11.3	505			
LWD129	11.4	506			
LWD130	11.3	507			
LWD131	11.3	508			
LWD132	11.4	509			
LWD133	11.4	510			
LWD134	11.3	511			
LWD135	11.3	512			
LWD136	11.3	513			
LWD137	11.4	514			
LWD138	11.4	515			
LWD139	11.4	516			
LWD140	11.4	517			
LWD141	11.4	518			
LWD142	11.2	519			
LWD143	11.2	520			
LWD144	11.2	521			
LWD145	11.2	522			
LWD146	11.2	523			
LWD147	11.4	524			
LWD148	11.3	525			
LWD149	11.3	526			
LWD150	11.2	527			
LWD151	11.3	528			
LWD152	11.3	529			
LWD153	11.3	530			
LWD154	11.3	531			
LWD155	11.4	532			
LWD156	11.3	533			
LWD157	11.3	534			
LWD158	11.4	535			
LWD159	11.3	536			
LWD160	11.4	537			
LWD161	11.4	538			
LWD162	11.4	539			
LWD163	11.3	540			

40 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 500

APOLDA, 21.07.2022

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SB-NR.: LWD ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :2

Auftrag/order/commande: 22-56943-1

Kunde/customer/client : GPG-GmbH

EUROCYLINDER SYSTEMS

Volumen/volume/volume V/l:	10 l
Prüfdruck/test pressure/pression d epreuve:	300 bar
Gasart/kind of gas/sorte du gaz:	Verd. Gas
Fülldruck/filling pressure/pression d service:	200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees:	0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWD164	11.4	541			
LWD165	11.3	542			
LWD166	11.3	543			
LWD167	11.4	544			
LWD168	11.4	545			
LWD169	11.4	546			
LWD170	11.3	547			
LWD171	11.3	548			

8 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 500

APOLDA, 21.07.2022

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SB-NR.: LWD ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :1

EUROCYLINDER SYSTEMS

Auftrag/order/commande: 22-57032-1

Kunde/customer/client : Rev Gas Industr

Volumen/volume/volume V/l:	10 l
Prüfdruck/test pressure/pression d epreuve:	300 bar
Gasart/kind of gas/sorte du gaz:	verd. Gas
Fülldruck/filling pressure/pression d service:	200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees:	0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWD172	11.3	1			
LWD173	11.3	2			
LWD174	11.3	3			
LWD175	11.3	4			
LWD176	11.3	5			
LWD177	11.3	6			
LWD178	11.2	7			
LWD179	11.2	8			
LWD180	11.3	9			
LWD181	11.3	10			
LWD182	11.3	11			
LWD183	11.3	12			
LWD184	11.3	13			
LWD185	11.3	14			
LWD186	11.3	15			
LWD187	11.3	16			
LWD188	11.3	17			
LWD189	11.3	18			
LWD190	11.3	19			
LWD191	11.3	20			
LWD192	11.3	21			
LWD193	11.3	22			
LWD194	11.3	23			

23 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 200

APOLDA, 21.07.2022

Ohne Unterschrift gültig. Valid without signature. Valable sans signature.

Traducere din limba engleză

MEDIMETER

Medimeter este un debitmetru destinat controlului şi măsurării debitului de aer sau oxigen administrat pacienţilor

Debitmetru MediMeter®

EDIŢIA 1/2011

AVANTAJE

- Suprafaţa plată a flotorului permite o citire uşoară şi sigură a valorilor debitului de către utilizatori
- Design ergonomic, uşor de curăţat
- Disponibil cu conector tată, cu montare pe şină şi furtun şi versiune dublă
- Mecanism de închidere uşor
- Flotor rezistent la impact
- Scală nouă - citire mai bună a valorilor de debit

Traducere din limba engleză

Date tehnice

Presiune gaz	O_2, aer
Game de debit	0 - 5 lpm 0 - 15 lpm 0 - 30 lpm
Conexiune intrare	conform standardului naţional
Conexiune ieşire	9/16” UNF, M12×1,25, G3/8, G 1/4 cu ştuţ furtun
Materialul corpului	Alamă nichelată
Garnituri inelare	EPDM
Buton de comandă	Poliamidă
Dimensiuni corp	Lăţime 32 mm Înălţime 160 mm Adâncime 60 mm Greutate 280 g (fără conector)
Gamă de temperatură:	
Depozitare	între - 30°C şi + 60°C
Funcţionare	între - 20°C şi + 60°C
Reglementări:	În conformitate cu directiva 93/42/CEE privind dispozitivele medicale În conformitate cu EN 15 002 (Dispozitive de măsurare a debitului pentru conectarea la prizele sistemelor de alimentare cu gaz medical)
Clasificare:	Clasa IIa
Producător:	GCE, s.r.o, Ž ižkova 381 583 81 Chotěboř, CZ
Marcaj CE	CE0434

Accesorii - UMIDIFICATOARE

Nr. art.	Descriere
K294432	MediWet 200 134°C G 3/8
K294416	MediWet 200 121°C G 3/8
K294402	MediWet 200 134°C G 9/16
K294401	MediWet 200 121°C G 9/16
K293498	MediWet 200 134°C 12 × 1,25
K293491	MediWet 200 134°C 12 × 1,25
K294452	MediWet 200 121°C G 1/4
K294435	MediWet 200 134°C G 1/4
K292254	MediWet 500 121°C M12 × 1,25

K294432

K292254

Gas Control Equipment

GCE la nivel global: http://www.gcegroup.com

Nr. art. 73510000525. Ediţia 1/2011 07022011md © 2011

Subsemnata **ŞTEFANA FORGACIU**, traducător autorizat de M. J. cu nr. **37629**,
certific exactitatea traducerii în limba română, cu textul înscrisului în copie, în limba engleză.

TRADUCĂTOR **ŞTEFANA FORGACIU** - *AUTORIZAT* cu nr. **37629**

DECLARATION OF CONFORMITY

for CE – marking according to Annex II of Medical Devices Directive 93/42/EEC

Manufacturer:

GCE s.r.o.
Žižkova 381
583 81 Chotěboř
CZECH REPUBLIC

The GCE s.r.o. herewith declares under his sole responsibility that the product

Product name:	Flow-metering devices
Model:	Mediflow + Mediflow II Medimeter MC315
Risk Classification:	IIa

is in conformity with applicable regulation

Directive:	MDD 93/42/EC, Annex II – 2007/47EC Amending
Quality Assurance Standards:	EN ISO 9001:2008 EN ISO 13485:2012
Procedural Standards:	EN ISO 15002-1:2006 EN 980:2008 EN ISO 14971:2012 EN 1041:2008

Product is in compliance with the requirements of Annex II the MDD 93/42/EEC and is safe for to be declared using in standard conditions.
Any modification to the product, not authorized by us, will invalidate this declaration.

EC Certificate No. 73547-2010-CE-CZS-NA 6.0 issued by by Det Norska Veritas, Veritasveien 1, 1322 Høvik, Norway, Notified Body No. 0434.

Date of Issue: 2015-09-01
Place of Issue: Chotěboř

Signature:
Quality Engineer: Vít Leszkow

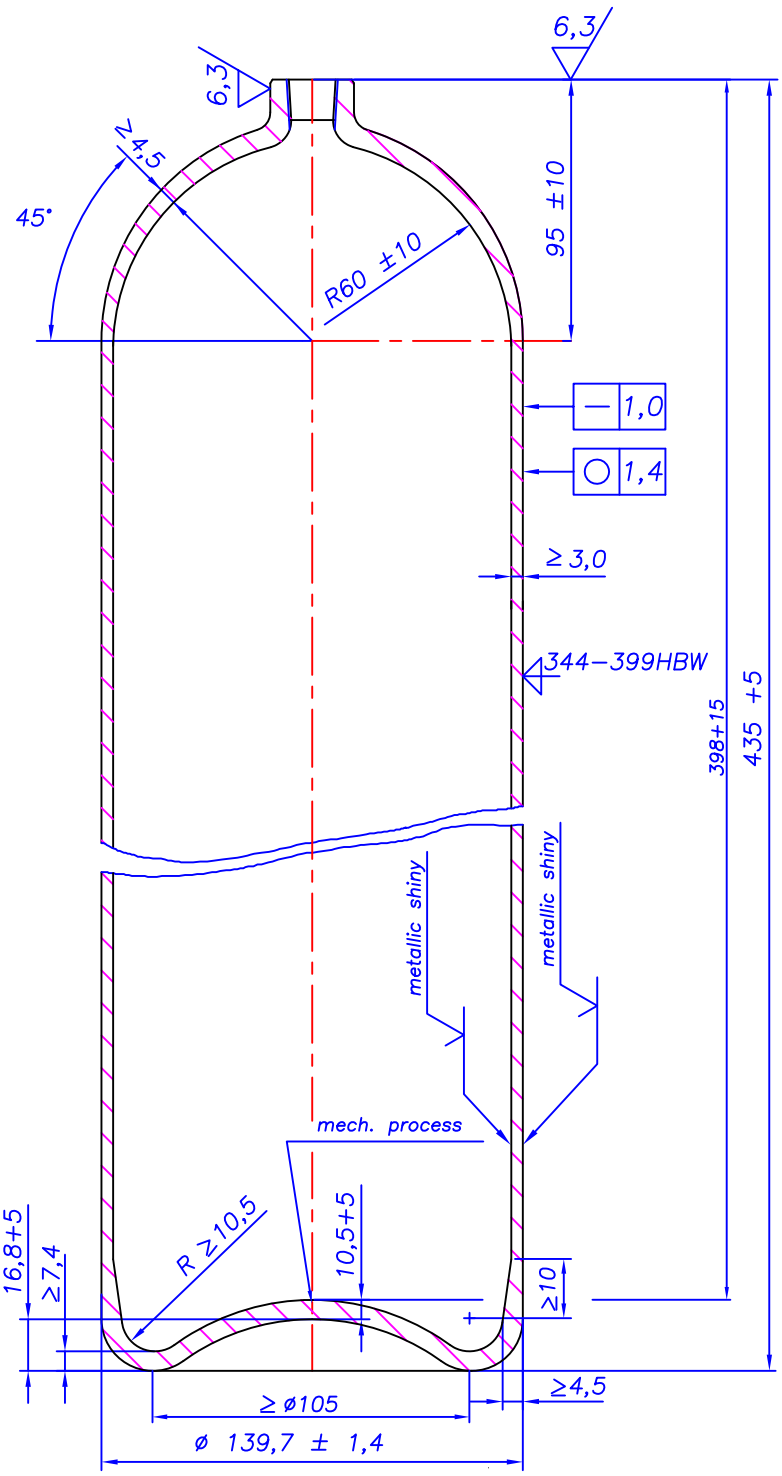
GCE, s.r.o.
Žižkova 381
583 81 Chotěboř
Czech Republic

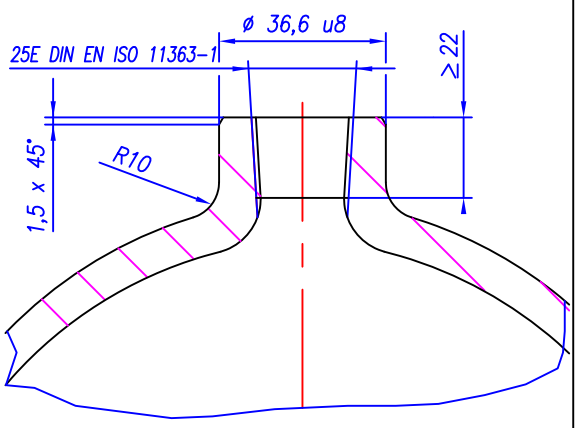
Tel. 00 420 569 661 111
Fax. 00 420 569 661 138

E-mail: gce@gcegroup.com
http:// www.gcegroup.com

VAT number: CZ27110991

size limit	allowance
36,6 u8	+ 0,099 + 0,060





hydro pressure test: Ph min. 30 s	ultrasonic test	Pb ≥ 480 bar	Py ≥ 401 bar	
Reg 850 MPa	Rm 980 – 1099 MPa	A>max{12500/Rm;14}%		

(name of gas)
Permanent and liquefied gases (except Methane, H2, CO and mixturers thereof)

(allowance)
DIN ISO 2768
– grob –

on a scale of ––––

weight appr. 5,5 kg

(material,semifinished part)
34CrMo4 (S<0,01%, P<0,02%, S+P<0,025%)
R 139,7 x 3,1 (Mw.+20%) DIN EN 10297-1

	date	name
2017		
editing:	19.12.	Seifert
constr.:		
techn.:		

(description)
Cylinder body 5l

(test pressure) 300 bar

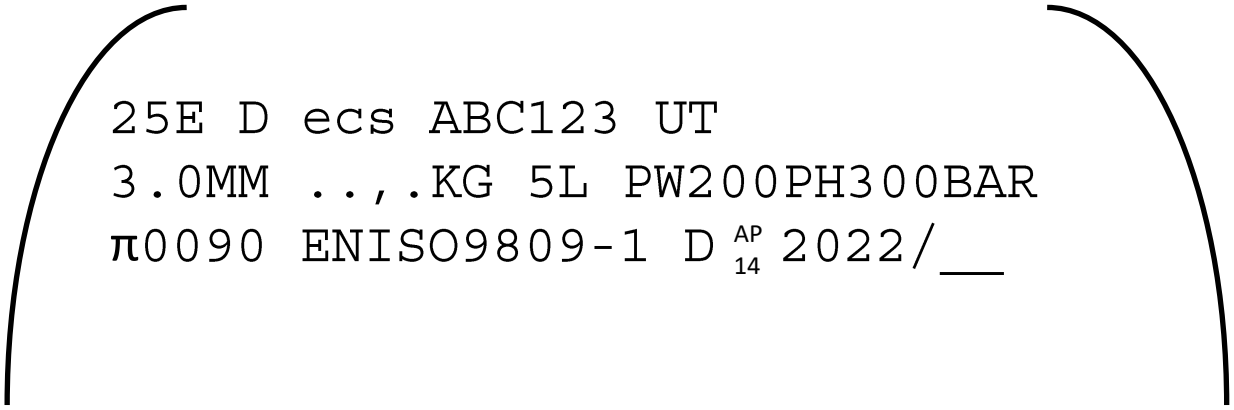
(regulation) DIN EN ISO 9809-1:2010/ ISO 9809-1:2010
(RL 2010/35/EU) 0090/EN49/12

(company)
ecs AG
eurocylinder systems

(drawing number)
13 052 147 7e

repl. of 17.03.2016

Front:



Back:

	17.03.2022	**Marking**
	Mund	REV 5L 57027
		Revision 0

eurocylinder systems AG • Auenstrasse 21 • D-99510 Apolda

Konformitätserklärung

Conformity declaration / Déclaration de conformité / Dichiarazione di conformità

Folgende Stahlflaschen wurden in Übereinstimmung mit der Richtlinie 2010/35/EU hergestellt.

The following steel cylinders were manufactured acc. directive 2010/35/EU.
Les bouteilles en acier suivantes ont été fabriquées en conformité avec la directive 2010/35/UE. Le bombole sono state prodotte secondo la direttiva 2010/35/UE.

Auftragsnummer: Order no / M. de commande / Ordine no:	22/57027/1
Kunde: Customer / Cliente / Client:	Rév Gas Industries Ltd.
Stückzahl: Quantity / Quantité / Quantità:	200
Fassungsraum: Volume / Volume / Volume:	5 l
Prüfdruck: Test pressure / Pression d'épreuve / Pressione Prova:	300 bar
Herstellernummern: Manufacturer's no. / No. di série / Numero de serie:	LWL101-LWL190, LWM001-LWM111 (excl.LWM024)
Kundennummern: Customer no / No. di cliente / Numero client:	-
Vorschrift: Rule / Règlementation / Regola:	EN ISO 9809 - 1 : 2010
Zulassungsnummer: Approval no / Numéro de agrément / Approvazione no:	0090/EN49/12
Konformitätszeichen: Conformity mark / No de conformité / Conformità no:	π
Kennnummer: Reference no / Numéro d'identification / Riferimento no:	0090

Apolda, 16.09.2022

i.A./pp. Förtsch
(ecs AG)

F10 Ausgabe 2 / 01.06.2022

eurocylinder systems AG
Auenstrasse 21, D-99510 Apolda
Tel: +49 (0) 3644 621 - 0
Fax: +49 (0) 3644 621 - 203

Vorstand:
Michael Dathe
Vorsitzender des Aufsichtsrates:
Daniel Spannagel

Sitz Apolda
Amtsgericht Jena: HRB 501 803
UST-Id-Nr.: DE150089541
St.-Nr.: 162/100/00856

UniCredit Bank AG
BLZ 820 200 87, Kto. 404 24 25
SWIFT-BIC: HYVEDEMM098
IBAN: DE04 8202 0087 0004 0424 25

Deutsche Bank AG
BLZ 820 700 00, Kto. 399 400 100
SWIFT-BIC: DEUTDE8E
IBAN: DE25 8207 0000 0399 4001 00

Landesbank Baden-Württemberg
BLZ 600 501 01
SWIFT-BIC: SOLADEST600
IBAN: DE39 6005 0101 0004 6603 98

Die Kennzeichnung mit P15Y durch die eurocylinder systems AG erfolgt im Auftrag nach den Vorgaben des Kunden. Die eurocylinder systems AG überprüft nicht, ob die rechtlichen Voraussetzungen für eine Kennzeichnung P15Y vorliegen. Es ist die ausschließliche Pflicht des Kunden und allen folgenden Eigentümern zu überprüfen, dass die einschlägigen Vorschriften der ADR/RID P200 eingehalten werden. Die eurocylinder systems AG ist nicht verantwortlich sicherzustellen, ob der Kunde und alle folgenden Eigentümer zu einer Kennzeichnung mit P15Y autorisiert sind oder ob die Voraussetzungen für die Kennzeichnung P15Y vorliegen.

The labeling with P15Y by eurocylinder systems AG is carried out in the order according to the customer's specifications. Eurocylinder systems AG does not check whether the legal requirements for a P15Y label are met. It is the sole responsibility of the customer and any subsequent owners to check that the relevant provisions of ADR/RID P200 are complied with. Eurocylinder systems AG is not responsible for ensuring whether the customer and all subsequent owners are authorized to label with P15Y or whether the requirements for labeling P15Y are met.

Le marquage avec P15Y par eurocylinder systems AG est effectué à la commande selon les spécifications du client. eurocylinder systems AG ne vérifie pas si les exigences légales pour une étiquette P15Y sont remplies. Il est de la seule responsabilité du client et des éventuels propriétaires ultérieurs de vérifier que les dispositions pertinentes de l'ADR/RID P200 sont respectées. eurocylinder systems AG n'est pas responsable de s'assurer que le client et tous les propriétaires ultérieurs sont autorisés à étiqueter avec P15Y ou si les exigences d'étiquetage P15Y sont remplies.

La marcatura con P15Y da parte di eurocylinder systems AG viene effettuata per conto del cliente secondo le specifiche del cliente. Eurocylinder systems AG non verifica se i requisiti legali per una marcatura P15Y sono soddisfatti. È dovere esclusivo del cliente e di tutti i successivi proprietari verificare che siano rispettate le disposizioni pertinenti dell'ADR/RID P200. Eurocylinder systems AG non è responsabile di garantire se il cliente e tutti i successivi proprietari sono autorizzati a etichettare P15Y o se i requisiti per la marcatura P15Y sono soddisfatti.

eurocylinder systems AG
Auenstrasse 21, D-99510 Apolda
Tel: +49 (0) 3644 621 - 0
Fax: +49 (0) 3644 621 - 203

Vorstand:
Michael Dathe
Vorsitzender des Aufsichtsrates:
Daniel Spannagel

Sitz Apolda
Amtsgericht Jena: HRB 501 803
UST-Id-Nr.: DE150089541
St.-Nr.: 162/100/00856

UniCredit Bank AG
BLZ 820 200 87, Kto. 404 24 25
SWIFT-BIC: HYVEDEMM098
IBAN: DE04 8202 0087 0004 0424 25

Deutsche Bank AG
BLZ 820 700 00, Kto. 399 400 100
SWIFT-BIC: DEUTDE8E
IBAN: DE25 8207 0000 0399 4001 00

Landesbank Baden-Württemberg
BLZ 600 501 01
SWIFT-BIC: SOLADEST600
IBAN: DE39 6005 0101 0004 6603 98

BEPD Betriebseigener Prüfdienst der eurocylinder systems AG
Inhouse inspection service of eurocylinder systems AG
Service de contrôle interne de eurocylinder systems AG

ecs AG eurocylinder systems

eurocylinder systems AG, Auenstraße 21, D-99510 Apolda ✆ + 49 (0) 36 44 - 62 1-0 + 49 (0) 36 44 - 62 12 03 www.eurocylinders.com

ZERTIFIKAT

CERTIFICATE / CERTIFICAT

über die Konformität der Herstellung gemäß RL 2010/35/EU, ADR/RID 2021, 1.8.7.4
of conformity of manufacture acc. to dir. 2010/35/EU ADR/RID 2021, 1.8.7.4
de conformité de la fabrication selon la dir. 2010/35/EU ADR/RID 2021, 1.8.7.4

Zertifikat-Nr., Certificate No., N° de certificate **: Π / LWL / 1123 / 2022**

Name und Anschrift des Herstellers / Fertigungsstätte: **eurocylinder systems AG**
Name and address of manufacturer/place of manufacture **Auenstraße 21**
Nom et adresse du fabricant / Lieu de fabrication: **99510 Apolda**

Hiermit wird bescheinigt, dass die ortsbeweglichen Druckgeräte die Anforderungen der RL 2010/35/EU und des ADR/RID 2021 erfüllen. Die Druckgeräte entsprechen den zur Baumusterzulassung eingereichten Unterlagen und sind mit dem abgebildeten Zeichen gekennzeichnet. This is to certify, that the transportable pressure equipment listed below meet the requirements of the Transportable Pressure Equipment Directive 2010/35/EU and the ADR/RID 2021. The pressure equipment complies the documents submitted for type approval and is marked with the following symbol. Nous certifions ci-joint que les appareils à pression mobiles sur différents lieux répondent aux exigences conformément à la directive 2010/35/EU et à la directive ADR/RID 2021. Les appareils à pression répondent aux contrôles des prototypes CE et sont caractérisés par les sigles représentés.

π 0090

Die Druckgeräte sind mit einem Ventil mit PI-Kennzeichnung auszurüsten.
The pressure devices are tob e fitted with a valve with PI-marking.
Les appareils à pression sont equips d´une vanne avec le caractére PI.

Geprüft nach Richtlinie 2010/35/EU, ADR/RID 2021: Tested under Directive 2010/35/EU, ADR/RID 2021 : Contrôlé selon la directive 2010/35/EU, ADR/RID 2021:	**Erstmalige Prüfung** Initial inspection and test Contrôle et épreuves initiaux
Prüfbericht-Nr.: Test report No.: Nr. de rapport de contrôle:	**LWL / 2022**
Herstell-Nr.: Manufacturer´s serial No.: Nr. du fabricant:	**LWL001 – LWL190, außer 043, 052, 056, 060, 081, 092**
Beschreibung des Druckgerätes: Description of pressure equipment: Description de l'appareil à pression:	**Nahtlose Stahlflaschen Familie EN 49 / 5,0 l** Seamless steel cylinder ...., family / l Surface en acier sans raccords ...., Famille / l
Norm: Standard: Standard:	**EN ISO 9809 – 1 : 2010**
Zertifikat-Nr. des Baumusters: Type certificate No.: Nr. de certificat du prototype:	**0090 / EN49 / 12**

Tropschug

Apolda, 15.09.2022
(Ort, Datum) (place, date)
Betriebseigener Prüfdienst der eurocylinder systems AG
Inhouse inspection service of eurocylinder systems AG,
Service de contrôle interne de eurocylinder systems AG

Der betriebseigene Prüfdienst ist zertifiziert durch die Benannte Stelle TÜV Thüringen e.V., Melchendorfer Str. 64, D-99096 Erfurt, Kennnummer 0090.
The inhouse inspection service is certified by the Notified Body TÜV Thüringen e.V., Melchendorfer Str. 64, D-99096 Erfurt, identification number 0090.
Le service d'inspection de la maison a été certifiée par l'organisme notifié TÜV Thüringen e.V., Melchendorfer Str. 64, D-99096 Erfurt, numéro d'identification 0090.

ecs eurocylinder systems	BEPD-Qualitätssicherungssystem **Prüfbericht** Inspection Report/rapport du test	Ausgabe: 3/02.01.2020	F007_01.1.1 Seite 1/2

Prüfberichts-nr.
Report-nr.
Rapport-n° L W L/2022

Zertifikat-nr. π /LWL/1123/2022
Certficate-nr. CE/ / /
N° de certificat

Glühlos/batch-nr./lot / Jahr/year/an

Volumen 5,0 dm³
Volume dm³
Volume dm³

Prüfdruck 300 bar
Test pressure bar
Pression d'épreuve bar

Abmessung 139,7 × 3,1
Dimensions
Dimensions

Gütepass 14 / 2022
Material certificate
Certificat matière

Zulassungs-Nr. 0090/EN49/12
Approved-nr.
N° d´homologation

Zeichnungs-Nr. 130521477
Drawing-nr.
Plan-n°

Chargen-Nr. 209965
Charge-nr.
Charge-n°

Prüflosgröße Stück
Inspection lot size pieces
Volume du lot de contrôle 202 pieces

Werkstoff 34CrMo4
Material
Matière

Chargen-Kennzeichnung grau
Charge identification
Identification de la charge

1. Angaben zur Wärmebehandlung
Information to the heat treatment
Informations concernant le traitment thermique

Vergüten/Quenching and tempering/Trempe et revenu

	°C	min
Austenitisieren Austenising Austénisation	880	10
Badtemperatur Bath temperature Température du bain	25 - 38	
Polymerkonzentration Polymer concentration Polymére concentration	% Kontrollwert 5,45 % % Check value % % Valeur contrôle %	
Anlassen Tempering Revenu	565	50

Arbeitsvorbereiter
Operations sheduler
Préparateur du travail i.A. 21.07.22
Unterschrift signing signature / Datum date date

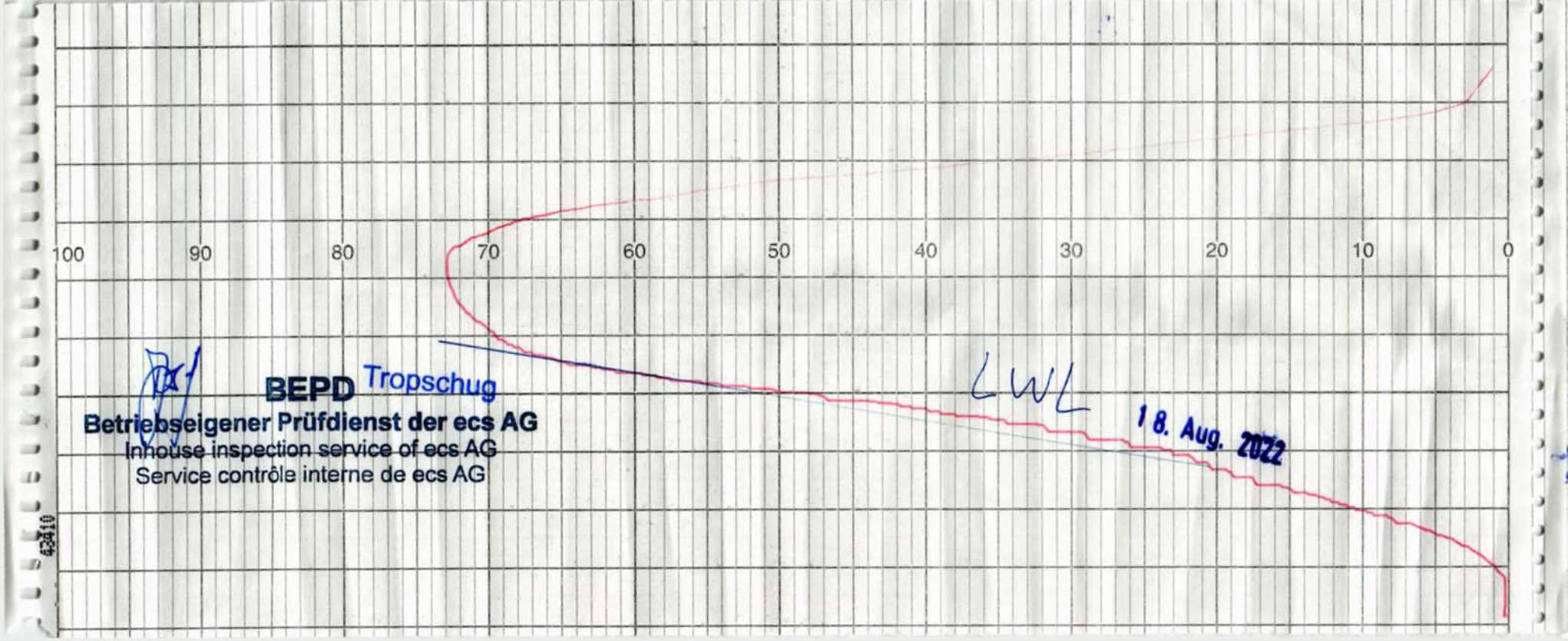
2. Bestätigung über die Einhaltung der technologischen Parameter
Compliance with technical parameters
Conformité des caractéristique techniques

Härter
Hardener
Trempeur i.A. Vigh-Hofmann 16.08.2022
Unterschrift signing signature / Datum date date

3. Ergebnis der Werkstoffprüfung (einschl. Berst-/Härteprüfung)
Result of the material test (inclusive bursting test/ hardness test)
Résultat du contrôle matière (incluse essai de rupture/test de dureté)

Vorgabewerte **erreicht / nicht erreicht**
Allowed values are / are not reached
Valeurs autorisées sont / ne sont pas atteintes

BEPD-WP
Inhouse inspection service
Service de contrôle interne 18. Aug. 2022
Unterschrift signing signature / Datum date date


100
90
80
70
60
50
40
30
20
10
0
BEPD Tropschug
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG
LWL
18. Aug. 2022
43410

Werkstoffprüfbericht/Material Test Report/Procés-verbal de contrôle matiére

Dieser Prüfbericht gehört zur Glühlos - Nr. LWL/2022 **und dem dazugehörigen Kontrollbericht.**
This test report is part of heat treatment batch- nr. ____ and the corresponding inspection report.
Le présent procés-verbal fait partie de no. de lot de traitement thermique____ et du procés-verbal de contrôle.

Volumen/Volume/Volume: 5,0 dm³ **Zulassung**/Approval/Permission: 0090/EN49/12

Ergebnisse der Werkstoffprüfung/Results of the material test/ Résultat du contrôle matiére:
nach DIN EN ISO 9809 – 1 : 2010 / nach DIN EN ISO 9809 – 2 : 2010

Zugversuch Tensile test Essai de traction	Abmessungen Dimensions Dimensions nach DIN EN ISO 6892 – 1 : 2017 B nach DIN EN ISO 6892 – 2 : 2017 B				Kraft Force Force N		ΔI mm	Härte an Prüfflasche Hardness of the test cylinder Dureté de la bouteille d' essai nach DIN EN ISO 6506–1:2015 [HB 30]
Prüftemp. Test temp. Temp. d'epreuve [°C]	Breite Width Largeur [mm]	Dicke Thickness Epaisseur [mm]	Fläche Area Surface [mm²]	Messlänge Measuring length Longueur de mesure [mm]	Streck-grenze Yield point Limite apparente d'elasticité [N/mm²]	Zugfestig-keit Tensile strength Résistance a' la traction [N/mm²]	Dehnung Elongation Allongement [%]	
20	20,0	3,5	70,0	45	67500 964	73000 1043	7,6 16,9	360

Kerbschlagbiegeversuch/ Impact test/ Essai de résilience nach DIN EN ISO 148 – 1 : 2011							Biegeversuch Bend test/ Essai de pliage nach DIN EN ISO 7438 : 2012 (D= 6 s ; 180°) 4 × ohne Anriss
Proben-Nr. Sample no. Numero d'echantillon	Breite Width Largeur [mm]	Höhe Height Hauteur [mm]	Fläche Area Surface [cm²]	Arbeit Work Travail [J]	Kerbschlag-zähigkeit Impact value Résilience [J/ cm²]	Mittelwert Mean value Valeur moyenne [J/ cm²]	
LWL.1	3,6	8,0	0,288	37,0	128	122	Hals – und Bodenprüfung Neck and bottom test Contrôle de col et fond
LWL.2	3,6	8,0	0,288	33,5	116		----------
LWL.3	3,6	8,0	0,288	35,5	123		
							Berstprüfung Bursting test/Essai de rupture
							568 bar

Probelage: Position of the sample/ Position de flexion	Längs / longitudinal
Prüftemperatur: Test temperature/ Temperature d'epreuve	-50°C
Kerbform: Form of the notch/ Form de l'entaille	V nach DIN EN ISO 148 – 1 : 2011
Kerbrichtung: Direction of the notch/ Direction de l'entaille	Senkrecht / perpendicular
Prüfmaschine : Test machine/ Machine d'essai	PS 30

Prüfer/ tester/ contrôleur
BEPD-WP
Apolda, 18.08.2022

Leitung BEPD
direction inhouse inspection service/service de contrôle interne
Unterschrift signing signature / Datum date date

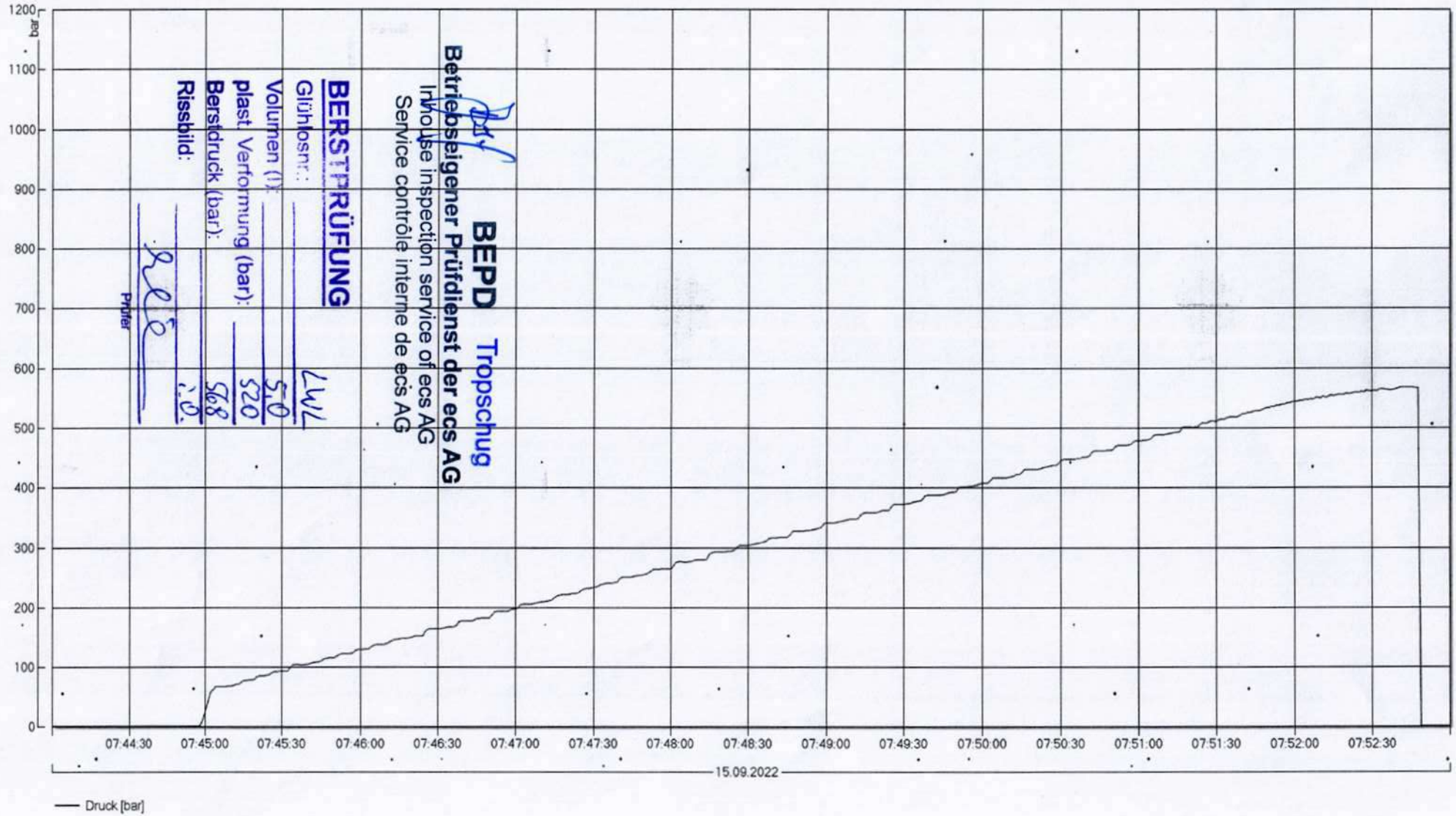
BEPD Tropschug
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG

Messwerte / Trend
Gerätename: Berstpruefung (Seriennummer J500F904428)
Zeitbereich: 15.09.2022 07:44:00 bis 15.09.2022 07:53:00

Vorlage: 2022-09
Glühlos LWL
Manometer Nr. 082502279

15.09.2022 11:53:41

ecs eurocylinder systems



EUROCYLINDER SYSTEMS AG

Parameter :lwl-5-0 29.01.13 - 00:06

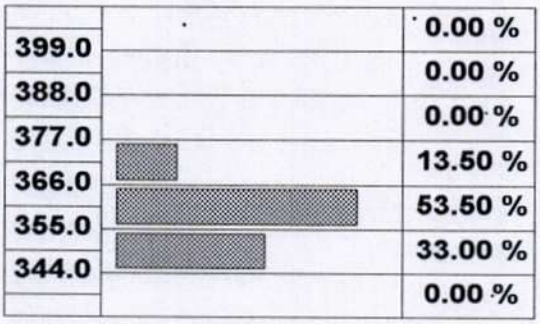
Chargen-Nr.	
SB-Nr.	LWL
Volumen	5,0
Fl.-Beh.-Typ	
Schicht	1
Anlagenfahrer	Felsberg
Prüfmethode	HB 30
Härteminimum	344
Härtemaximum	399

Meßwerte/Flasche	1
Meßwerte gesamt	200
Losanzahl	200
Anzahl Klassen	5
Anzahl Härteverlauf	100

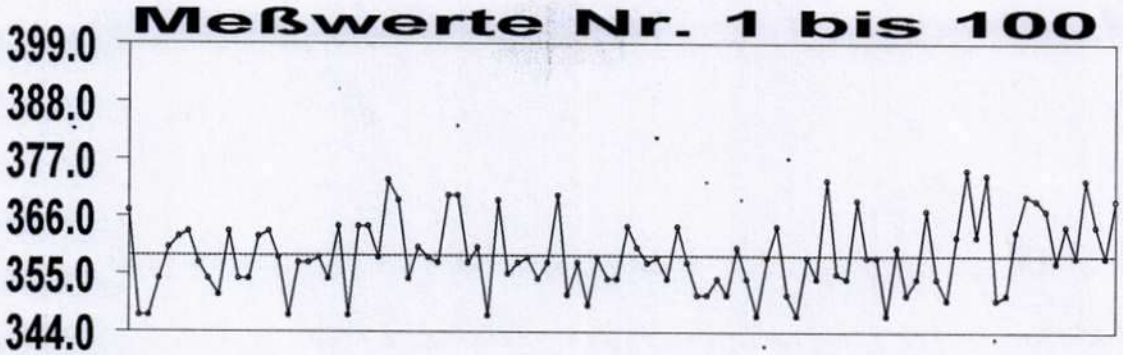
Statistikwerte :[HB 30]

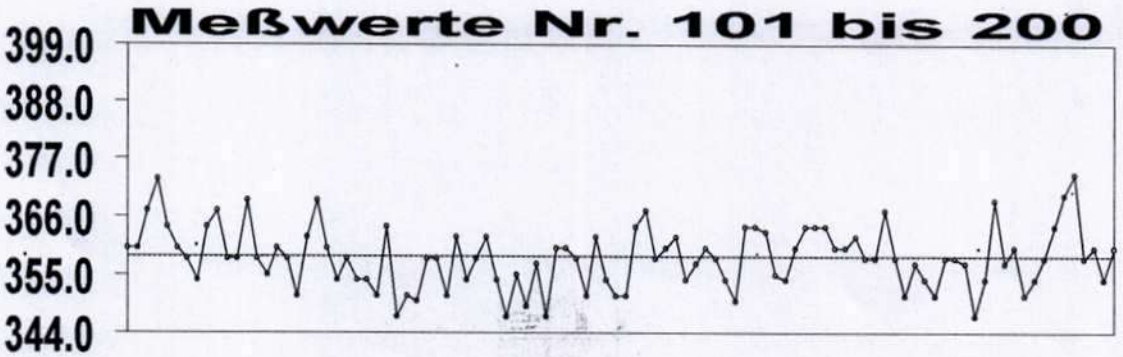
Gesamtanzahl	:	200
Anzahl in Grenzen	:	200
Anzahl zu weich	:	0
Anzahl zu hart	:	0
Anzahl ST	:	200
kleinster Wert	:	347.0
größter Wert	:	375.0
Xquer	:	358.380
Standardabweichung	:	6.434

Histogramm :



Härteverlauf :[HB 30]





BEPD Tropschug
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG

Datum: 15. Sep. 2022 Unterschrift: _____

KARL DEUTSCH

Gesamtprotokoll

STFL ECHOGRAPH 1155 [55281]

ECS AG EUROCYLINDER SYSTEMS

Datum des Ausdrucks: 14.09.2022 20:24:54

Prüflose-Nr.	LWL
Abmessung	139,7x3,0
Werkstoff	34CrMo4
Charge	209965
Prüfspezifikation	ENISO 9809-1

letztes Pruefdatum: 14.09.2022 20:22:45

Pruefdaten:

Programm: 140-5-130521477.dat(0.TE)

Parameter-Auswahl:

USEL: 140x3,0.usel(0.TE)

DAV: 600.dav(0.TE)

Ultraschall

Ultraschall1

Ultraschall2

Ultraschall3

Ultraschall4

Ultraschall5

Statistik:

	Stueck	%	Laenge [m]	%
Gesamt:	192	100.00	417.26	100.00
Gut:	192	100.00	417.26	100.00
auffällig/Wiederholungsprü.	0	0.00	0.00	0.00
unsichere Kopplung	0	0.00	0.00	0.00

BEPD Tropschug

Unterschrift:

Betriebseigener Prüfdienst der ecs AG
In-house inspection service of ecs AG
Service contrôle interne de ecs AG

[redacted]	BEPD-Qualitätssicherungssystem Wasserdruckprüfung	Ausgabe: 1/01.05.2014	F011_01.1.1

Bescheinigung über die Durchführung der Wasserdruckprüfung

Certificate about the realisation of the hydraulic test
Certificat sur la mise en œuvre de l'examen de pression hydraulique

Los / Batch / Lot: LWL

Prüfdruck / Test pressure / Pression d'essai: 300 bar (Manometer Nr.: 121502075)

Stückzahl / Piece no. / No. de pièces: 200 gut / good / bonnes: 198 schlecht / defect / rebut: 2

Die Stahlflaschen wurden mit dem Prüfdruck beaufschlagt. Bei den für gut befundenen Stahlflaschen zeigten sich keine Undichtigkeiten und keine bleibenden Verformungen.
The cylinders have been impinged with the test pressure. In case of the as good considered steel cylinders were no leakages and permanent deformations. / Les bouteilles en acier ont été soumises à la pression d'essai. Les bouteilles en acier considérées comme bonnes ne présentent aucune fuite ni aucune déformation permanente.

Volumenermittlung / Determination of volume / Détermination du volume

Bei 10 % der Stahlflaschen des Loses wurde das Volumen ermittelt.
The volume of 10 % of the steel cylinders from the lot was determined./ Le volume de 10 % des bouteilles en acier a été déterminé.

Volumen (min.)/ Volume (min.) : 5,0 l

Lfd.Nr./ Serial no./No.cour.	Volumen(l)/ Volume(l)	Lfd.Nr./ Serial no./No.cour.	Volumen(l)/ Volume(l)
01	5,1	11	5,1
02	5,1	12	5,1
03	5,1	13	5,1
04	5,1	14	5,1
05	5,1	15	5,1
06	5,1	16	5,1
07	5,1	17	5,1
08	5,1	18	5,1
09	5,1	19	5,1
10	5,1	20	5,1

Der Prüfer bestätigt die Prüfung und Einhaltung der Anforderungen nach Kontrollvorschrift KV011_01 bezüglich Sichtprüfung der Außenseite, Innenbesichtigung, Gewindeprüfung, Maßkontrolle und Fußringsitz. / The tester confirm the check and the compliance in terms of the requirements to test direction KV011_01 regarding external visual testing, internal visual testing, thread test, dimensional inspection and base ring fit. L'inspecteur confirme la vérification et la conformité avec les exigences de contrôle KV011_01 concernant l'inspection visuelle à l'extérieur et à l'intérieur, contrôle de taraudage, contrôle dimensionnel et que la bague de pièd convient.

BEPD-WPS/US
inhouse inspection service
service de contrôle interne

i.A. Kaiser 14.09.2022
Unterschrift signing signature / Datum date date

Leitung BEPD
direction inhouse inspection service
service de contrôle interne

Unterschrift signing signature / Datum date date

BEPD Tropschug
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG

SB-NR.: LWL ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :1

Auftrag/order/commande: 22-57123-1

Kunde/customer/client : Sauerstoffw. Gu

EUROCYLINDER SYSTEMS AG

Volumen/volume/volume V/l:	5 l
Prüfdruck/test pressure/pression d epreuve:	300 bar
Gasart/kind of gas/sorte du gaz:	Sauerstoff
Fülldruck/filling pressure/pression d service:	200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees:	0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWL001	7.05	527322			
LWL002	7.06	527323			
LWL003	7.05	527324			
LWL004	7.06	527325			
LWL005	7.05	527326			
LWL006	7.06	527327			
LWL008	7.06	527329			
LWL009	7.06	527330			
LWL007	7.07	527328			
LWL010	7.07	527331			
LWL011	7.07	527332			
LWL012	7.09	527333			
LWL013	7.07	527334			
LWL014	7.06	527335			
LWL015	7.07	527336			
LWL016	7.06	527337			
LWL017	7.05	527338			
LWL018	7.06	527339			
LWL019	7.06	527340			
LWL020	7.05	527341			
LWL021	7.04	527342			
LWL022	7.03	527343			
LWL023	7.03	527344			
LWL024	7.08	527345			
LWL025	7.02	527346			
LWL026	7.01	527347			
LWL027	7.02	527348			
LWL028	7.02	527349			
LWL029	7.09	527350			
LWL030	7.06	527351			
LWL031	7.03	527352			
LWL032	7.02	527353			
LWL033	7.03	527354			
LWL034	7.07	527355			
LWL036	7.07	527357			
LWL035	7.06	527356			
LWL038	7.02	527359			
LWL037	7.02	527358			
LWL039	7.08	527360			
LWL040	7.07	527361			

40 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 100

APOLDA, 16.09.2022

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SB-NR.: LWL ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :2

Auftrag/order/commande: 22-57123-1

Kunde/customer/client : Sauerstoffw. Gu

Volumen/volume/volume V/l:	5 l
Prüfdruck/test pressure/pression d epreuve:	300 bar
Gasart/kind of gas/sorte du gaz:	Sauerstoff
Fülldruck/filling pressure/pression d service:	200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees:	0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWL041	7.02	527362			
LWL042	7.03	527363			
~~LWL043~~	~~6.84~~	~~527364~~			
LWL044	6.86	527365			
LWL045	6.90	527366			
LWL046	7.06	527367			
LWL047	6.98	527368			
LWL048	7.02	527369			
LWL049	7.01	527370			
LWL050	7.01	527371			
LWL051	7.03	527372			
~~LWL052~~	~~7.07~~	~~527373~~			
LWL053	7.06	527374			
LWL054	7.05	527375			
LWL055	7.02	527376			
~~LWL056~~	~~7.02~~	~~527377~~			
LWL057	7.06	527378			
LWL058	7.03	527379			
LWL059	7.05	527380			
~~LWL060~~	~~7.09~~	~~527381~~			
LWL061	7.06	527382			
LWL062	7.00	527383			
LWL063	7.05	527384			
LWL064	7.06	527385			
LWL065	7.06	527386			
LWL066	7.01	527387			
LWL067	7.07	527388			
LWL068	7.03	527389			
LWL069	7.03	527390			
LWL070	7.03	527391			
LWL071	7.06	527392			
LWL072	7.07	527393			
LWL073	7.06	527394			
LWL074	7.03	527395			
LWL075	7.04	527396			
LWL076	7.04	527397			
LWL077	7.03	527398			
LWL078	7.02	527399			
LWL079	7.02	527400			
LWL080	7.01	527401			

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40 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 100

APOLDA, 16.09.2022

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SB-NR.: LWL ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :3

Auftrag/order/commande: 22-57123-1

Kunde/customer/client : Sauerstoffw. Gu

Volumen/volume/volume V/l:	5 l
Prüfdruck/test pressure/pression d epreuve:	300 bar
Gasart/kind of gas/sorte du gaz:	Sauerstoff
Fülldruck/filling pressure/pression d service:	200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees:	0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
~~LWL081~~	~~7.02~~	~~527402~~			
LWL082	7.02	527403			
LWL083	7.03	527404			
LWL084	6.89	527405			
LWL085	7.00	527406			
LWL086	7.01	527407			
LWL087	7.04	527408			
LWL088	7.07	527409			
LWL089	7.08	527410			
LWL090	7.10	527411			
LWL091	6.91	527412			
~~LWL092~~	~~6.85~~	~~527413~~			
LWL093	7.06	527414			
LWL094	7.04	527415			
LWL095	7.01	527416			
LWL096	7.04	527417			
LWL097	7.02	527418			
LWL098	6.86	527419			
LWL099	7.07	527420			
LWL100	7.07	527421			

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20 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 100

APOLDA, 16.09.2022

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SB-NR.: LWL ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :1

Auftrag/order/commande: 22-57027-1

Kunde/customer/client : Rev Gas Industr

Volumen/volume/volume V/l:	5 l
Prüfdruck/test pressure/pression d epreuve:	300 bar
Gasart/kind of gas/sorte du gaz:	verd. Gas
Fülldruck/filling pressure/pression d service:	200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees:	0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWL101	7.06	1			
LWL102	7.04	2			
LWL103	7.06	3			
LWL104	7.05	4			
LWL105	7.07	5			
LWL106	7.07	6			
LWL107	7.07	7			
LWL108	7.08	8			
LWL109	7.04	9			
LWL110	7.00	10			
LWL111	7.07	11			
LWL112	7.06	12			
LWL113	7.06	13			
LWL114	7.07	14			
LWL115	7.08	15			
LWL116	7.05	16			
LWL117	7.06	17			
LWL118	7.06	18			
LWL119	7.02	19			
LWL120	7.05	20			
LWL121	7.06	21			
LWL122	7.06	22			
LWL123	7.07	23			
LWL124	7.07	24			
LWL125	7.07	25			
LWL126	7.03	26			
LWL127	7.04	27			
LWL128	7.04	28			
LWL129	7.02	29			
LWL130	7.02	30			
LWL131	7.02	31			
LWL132	7.04	32			
LWL133	7.04	33			
LWL134	7.05	34			
LWL135	7.07	35			
LWL136	7.02	36			
LWL137	7.06	37			
LWL138	7.05	38			
LWL139	7.05	39			
LWL140	7.05	40			

40 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 200

APOLDA, 14.09.2022

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SB-NR.: LWL ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :2

EUROCYLINDER SYSTEMS

Auftrag/order/commande: 22-57027-1

Kunde/customer/client : Rev Gas Industr

Volumen/volume/volume V/l:	5 l
Prüfdruck/test pressure/pression d epreuve:	300 bar
Gasart/kind of gas/sorte du gaz:	verd. Gas
Fülldruck/filling pressure/pression d service:	200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees:	0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWL141	7.04	41			
LWL142	7.02	42			
LWL143	7.05	43			
LWL144	7.06	44			
LWL145	7.05	45			
LWL146	7.05	46			
LWL147	7.03	47			
LWL148	7.06	48			
LWL149	7.07	49			
LWL150	7.07	50			
LWL151	7.05	51			
LWL152	7.05	52			
LWL153	7.09	53			
LWL154	7.07	54			
LWL155	7.05	55			
LWL156	7.04	56			
LWL157	7.07	57			
LWL158	7.07	58			
LWL159	7.03	59			
LWL160	7.04	60			
LWL161	7.05	61			
LWL162	7.02	62			
LWL163	7.03	63			
LWL164	7.08	64			
LWL165	7.08	65			
LWL166	7.08	66			
LWL167	7.07	67			
LWL168	7.08	68			
LWL169	7.05	69			
LWL170	7.08	70			
LWL171	7.08	71			
LWL172	7.07	72			
LWL173	7.07	73			
LWL174	7.04	74			
LWL175	7.07	75			
LWL176	7.05	76			
LWL177	7.06	77			
LWL178	7.07	78			
LWL179	7.04	79			
LWL180	7.08	80			

40 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 200

APOLDA, 14.09.2022

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SB-NR.: LWL ORGINALLISTE/ORGINAL LIST/RELEVE ORGINAL SEITE :3

Auftrag/order/commande: 22-57027-1

Kunde/customer/client : Rev Gas Industr

Volumen/volume/volume V/l:	5 l
Prüfdruck/test pressure/pression d epreuve:	300 bar
Gasart/kind of gas/sorte du gaz:	verd. Gas
Fülldruck/filling pressure/pression d service:	200 bar
Masse Anbauteile/mass of add-on pieces/poids pieces montretees:	0 Kg

Behälter/ cylinder/ bouteille Nr./No.	Leermasse/ empty weight/ poids vide m/kg	Kunde/ customer/ client Nr./No	Tara m/kg	Volumen/ volume/ volume V/l	Bemerkungen/ Remarks/ notes
LWL181	7.04	81			
LWL182	7.06	82			
LWL183	7.02	83			
LWL184	7.04	84			
LWL185	7.06	85			
LWL186	7.05	86			
LWL187	7.05	87			
LWL188	7.05	88			
LWL189	7.09	89			
LWL190	7.06	90			

10 STÜCK / PIECES / PIECES VON INSGESAMT/ OF TOTAL/ D AU TOT/ 200

APOLDA, 14.09.2022

Ohne Unterschrift gültig. Valid without signature. Valable sans signature.

Geanta pentru depozitarea si transportul buteliei de oxigen
TB 100

Descriere:

Geanta de oxigenoterapie Versapak TB 100 este special conceputa pentru a transporta butelii de oxigen de până la 5 litri (inclusiv reductorul de presiune), precum și toate materialele necesare pentru a aplica terapia cu oxigen, adică Pipe Guedel, sonde endotraheale, laringoscop, masca oxigen, kit de resuscitare, etc. Geanta este inscriptionata de jur imprejur cu benzi reflectorizante pentru a putea fi reperata cu usurinta pe timp de noapte. Geanta este prevazuta cu o fereastra transparenta pentru a putea vizuliza presiunea oxigenului fara a fi necesara scoaterea buteliei din geanta.

Caracteristici tehnice:

- Dimensiune: 65 x 22 cm
- Capacitate: 25,28 L
- Greutate: 1.58 kg
- Material: 600D Polyester
- Colour EB02.016: Rosu
- Capacitate incarcare: 15 kg

VERSAPAK CONTACT

Loc. Macău FN, Com. Aghireșu, jud. Cluj, România

Email: sales@versapak.ro
office@versapak.ro

Telefon: 0743.088.323
0264/284140

Fax: 0264/284136

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

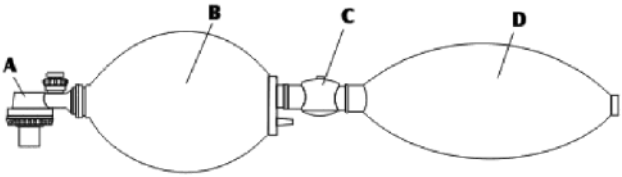
PROFESSIONAL MEDICAL PRODUCTS

BALOANE AUTOCLAVABILE SILICON

Manualul Utilizatorului

Principii de funcționare

Vedere de ansamblu a unui sistem de respirație
(A) Valva inferioara (B) Balon Silicon (C) Valva Rezervor (D) Rezervor Oxigen.
Valva rezervorului și rezervorul de oxigen trebuie îndepărtate dacă nu se furnizeaza oxigen suplimentar.



Dispozitiv Medical conform cu Directiva 93/42/EEC

REF **34244 - 34245 - 34246 - 34247**

CE **0476**

Gima S.p.A.
Via Marconi, 1
20060 Gessate (MI) Italy
Made in Taiwan

M34244-M-Rev.5-01.20

Descrierea produsului și utilitatea

Balonul de ventilatie manual GIMA este conceput pentru a fi utilizat ca adjuvant la respirație artificială și resuscitare cardiopulmonară. Balonul poate fi utilizat pentru a ventila pacientul cu apnee și pentru a crește ventilația și pentru furnizarea de oxigen la pacientul care respiră spontan. Design-ul este, de asemenea, diferit în funcție de adult, copil sau sugar, folosind o frecvență diferită de comprimare, ele vin cu dimensiuni diferite pentru a satisface nevoia de oxigen a tuturor pacienților.
Codurile 34244, 34246 și 34247 sunt echipate cu o supapă POP-Off, modelul cod 34245 nu include supapa POP-Off în echiparea standard.
Mărimea adultă are un design cu supapă de reducere a presiunii (opțional). Când presiunea din interiorul pungii depășește 60 cmH20 și 40 cmH20 pentru sugar și sacul pentru copii, supapa de reducere a presiunii va evacua automat aerul eliberat în atmosferă pentru a proteja plămânul de rănire din cauza presiunii ridicate.
Acest produs este destinat utilizării de către personal medical calificat sau personal de urgență instruit în ventilația pulmonară și tehnici avansate de susținere a vieții cardiace.

GIMA Balon de Silicon
Este fabricat folosind silicon de calitate superioară, cu flexibilitate ridicată, material stabil, poate rezista la temperaturi ridicate (până la maximum 134°C).

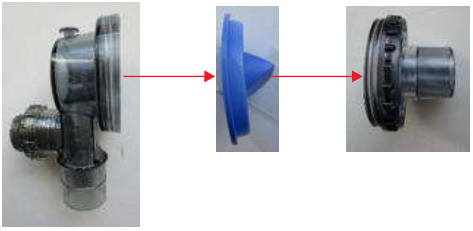
Vedere de ansamblu

34244

34245 – 34246 - 34247

1

2



Specificatii si Performanta

Temperatura Stocare: -40°C (-40°F) la 60°C (140°F)
Temperatura Operare: -18°C (0°F) la 50°C (122°F)

Materiale

Cauciuc siliconic
rezervor de silicon
valva inferioara
valva cu clapete
valva etansare
masca infant
masca copil
masca adult
elastic masca
O-inel

Policarbonat
carcasa supapei non-respiratie
carcasa supapei de intrare a sacului
carcasa supapei rezervorului
conector pentru sac rezervor
carcasa masca adult
carcasa valvei de presiune
tija valvei

Clorura de polivinil
rezervor de oxigen

Oţel inoxidabil
arc supapei de eliberare a presiunii

Connectori

port pacient:	15 mm I.D. (F) / 22 mm O.D. (M)
INTRARE SAC SILICON	23 mm I.D. (M)
supapa rezervorului	25 mm I.D.
orificiul supapei de admisie	25 mm O.D.
Intrare suplimentară de gaz	6 mm O.D. (M)

Specificațiile tehnice și caracteristicile de performanță ale dispozitivului

Spatiu mort

valva	7 mL
masca adult	150 mL
masca copil	95 mL
masca infant	28 mL

Valva eliberare presiune
Copil si infant 40±5 cmH_2O
Adult 60±10 cmH_2O

Volumul vascular de 1350 ml poate fi atins folosind două mâini

Rata minimă de ciclu
Adult – 20 respiratii/min
Copil - 20 respiratii /min
Infant - 40 respiratii /min

Concentrația de oxigen
cu rezervor 99%
fara rezervor 45% (adult si copil)
90% (infant)

Caracteristicile de performanță pentru baloanele de ventilatie manuala vor varia de la utilizator la utilizator, în funcție de o varietate de factori: temperatura ambiantă, structura plămânilor pacientului, frecvența ventilației, dimensiunea mâinilor operatorului..

Interval de presiune livrata
Adult: 60±10 cmH_2O maxim (se poate depasi de către operator)
Copil si Infant: 40±5 cmH_2O maxim (se poate depasi de către operator)

Interval de volum al ciclului

	Folosind o mana	Folosind doua maini
Adult	700 ml	900 ml
Copil	300 ml	350 ml
Infant	150 ml	225 ml

Procesul de curățare-dezinfectie-sterilizare
Următorii pași sunt recomandați. Selectați metodele adecvate pentru piesele din sistemul de ventilatie în cauză conform tabelului.

Metode aplicate	**Curatare (Spalare)**		**Dezinfectie**			**Sterilizare**	
Parti	Spalare manuala	Spalare automata (WM)	WM dizinfectie	Fierbere	Chemicale	121°C (244°F) Policarbonat	134°C (273°F) Polisulfura
A: Valva inferioara	●	●	●	●	●	Policarbonat ●	Polisulfura ●
B: Corp balon	●	●	●	●	●	●	●
C: Valva rezervor	●	●	●	●	●	Policarbonat ●	Polisulfura ●
D:Rezervor oxigen	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯
E: Tub oxigen	▯	▯	▯	▯	▯	▯	▯
F: Masca	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯	Silicon: ● PVC: ▯

: aplicabil ▯: non aplicabil

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PROFESSIONAL MEDICAL PRODUCTS

MASCHERINA FACCIALE IN SILICONE
SILICONE FACE MASK

Manuale d'uso - User manual

REF	DESCRIPTION
34223	Face mask N° 3 - child/large
34224	Face mask N° 4 - adult/small
34225	Face mask N° 5 - adult/large

CAUTION

1. Read the instructions for use before use.
2. Federal Law (USA) restricts this device to sale by or on the order of a physician.
3. Patient should be monitored constantly whenever this device is in use.

DIRECTIONS FOR USE

1. Check for clear airflow passage prior to use.
2. Connect to breathing circuit or resuscitation device with appropriate fitting.
3. Make sure all connections are compatible and fit firmly.
4. Hand-hold or secure with head strap.

CLEANING AND STERILIZATION

1. Cleaning (Manual)

a. Rinse neutral detergent to all surface of mask.
b. Use brush to clean mask.
c. Wash mask under the cleaning running water until mask is cleaned completely.
d. Dry it in the room temperature or 50°C oven.

2. Sterilize the components using one of the following methods:

a. Autoclave (max 121°C following sterilizer's instructions)
b. Most common disinfecting solutions which are used for equipment coming into contact with the patient. Rinse thoroughly with water after sterilization.

STORAGE

1. Store in clean dry conditions. Away from heat and light.
2. The temperature for storage and transport is between -20°C and 60°C.

Simboli / Symbols					
CE	Dispositivo medico conforme alla Direttiva 93/42/CEE Medical Device complies with Directive 93/42/EEC	REF	Codice prodotto Product code		Data di scadenza Expiration date
	Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso Caution: read instructions (warnings) carefully		Fabbricante Manufacturer		Conservare in luogo fresco ed asciutto Keep in a cool, dry place
	Leggere le istruzioni per l'uso Consult instructions for use		Data di fabbricazione Date of manufacture		Conservare al riparo dalla luce solare Keep away from sunlight
LOT	Numero di lotto Lot number				

REF **34223 - 34224 - 34225**

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Made in Taiwan

CE 0476

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PROFESSIONAL MEDICAL PRODUCTS

MASCHERINA FACCIALE IN SILICONE
SILICONE FACE MASK

Manuale d'uso - User manual

REF	DESCRIPTION
34220	Face mask N° 0 - infant/small
34221	Face mask N° 1 - infant/large
34222	Face mask N° 2 - child/small

CAUTION

1. Federal Law (USA) restricts this device to sale by or on the order of a physician.
2. Patient should be monitored constantly whenever this device is in use.
3. Store in clean dry conditions away from heat and light.

DIRECTIONS FOR USE

1. Check for clear airflow passage prior to use.
2. Connect to breathing circuit or resuscitation device with appropriate fitting.
3. Make sure all connections are compatible and fit firmly.
4. Hand-hold or secure with head strap.

CLEANING AND STERILIZATION

Sterilize the components using one of the following methods:

a. Autoclave (max 134°C following sterilizer's instructions)
b. Ethylene oxide (following sterilizer's instructions)
c. Most common disinfecting solutions which are used for equipment coming into contact with the patient. Rinse thoroughly with water after sterilization.

Simboli / Symbols					
CE	Dispositivo medico conforme alla Direttiva 93/42/CEE Medical Device complies with Directive 93/42/EEC	REF	Codice prodotto Product code		Data di scadenza Expiration date
	Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso Caution: read instructions (warnings) carefully		Fabbricante Manufacturer		Conservare in luogo fresco ed asciutto Keep in a cool, dry place
	Leggere le istruzioni per l'uso Consult instructions for use		Data di fabbricazione Date of manufacture		Conservare al riparo dalla luce solare Keep away from sunlight
LOT	Numero di lotto Lot number				

REF **34220 - 34221 - 34222**

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Made in Taiwan

CE 0476

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Modello / Model:

Palloni rianimatori in silicone / Kit Palloni rianimatori in silicone adulti / Silicone resuscitators / Adult silicone resuscitators kit
Codici / Codes:

34245, 34246, 34247; 34248, 34277, 34249 ; 34244

Modello / Model:

Reservoir monouso (sacche ossigeno) e valvola / Oxygen reservoir and valve
Codici / Codes:

34257; 34258; 34275; 34279

Modello / Model:

Valvola PEEP e adattatore / Valvola antireflusso e posteriore / Peep valve and adapter / Non-rebreathing valve and intake valve
Codici / Codes:

34227 ; 34228 ; 34259 ; 34256

Tipologia / *Medical Devices:*
Dispositivi per terapia termica / *Thermic therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1403

Modello / Model:

Ghiaccio istantaneo TNT / PE / TNT / PE instant ice cold pack
Codici / Codes:

34110 ; 34111

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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Tel +39.051.459.3.111
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E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

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DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY

La Società GIMA S.P.A., con sede a GESSATE (MI), Via Marconi 1, in qualità di fabbricante dei dispositivi medici:
We undersigned GIMA S.p.A., with head office addressed in Gessate (MI), Via Marconi 1, as the manufacturer of medical devices:

Dispositivi medici / *Medical Devices*	**Codici/*Ref. #***
PALLONI RIANIMATORI autoclavabili / *Autoclavable Resuscitators*	34245, 34246, 34247
PALLONI RIANIMATORI monouso / *Disposable Resuscitators*	34248, 34277, 34249
KIT PALLONE SILICONE ADULTI / *Silicone Resuscitators kit adult*	34244
MASCHERE IN SILICONE AUTOCLAVABILI / *Silicone autoclavable face masks*	34220, 34221, 34222, 34223, 34224, 34225
MASCHERE AUTOCLAVABILI ANESTESIA GIMA PLUS / *GIMA PLUS autoclavable anesthesia face masks*	34252, 34253, 34254, 34255, 34250
VALVOLA PEEP / *PEEP VALVE*	34227
VALVOLA ANTIREFLUSSO / *Non-Rebreathing valve*	34259
ADATTATORE VALVOLA PEEP / *PEEP VALVE ADAPTER*	34228
VALVOLA POSTERIORE / *Rear valve*	34256
RESERVOIR MONOUSO (sacche ossigeno) / *Single use reservoire (oxygen bags)*	34257, 34258, 34275, 34279

appartenenti alla classe di rischio IIa in accordo alla regola 2 dell'Allegato IX, della Direttiva 93/42/CEE e ss.mm.ii. (recepita in Italia con D.lgs. 46/97, e ss.mm.ii.),
risk class IIa, according to rule 2 of the Annex IX, Directive 93/42/EEC and subsequent amendments and integrations (enforced in Italy by Leg. Decree No. 46/97 and subsequent amendments and integrations),

Dispositivi medici / *Medical Devices*	**Codici/*Ref. #***
MASCHERE LARINGEE RIUTILIZZABILI / *Reusable laringeal masks*	34424, 34425, 34426, 34427, 34428, 34429
CANNULE DI GUEDEL STERILI / *Sterile guedel airways*	34431, 34432, 34433, 34434, 34435, 34436, 34437, 34438, 34439, 34383

appartenenti alla classe di rischio IIa in accordo alla regola 5 dell'Allegato IX, della Direttiva 93/42/CEE e ss.mm.ii. (recepita in Italia con D.lgs. 46/97, e ss.mm.ii.), dichiara sotto la propria esclusiva responsabilità, che tali dispositivi:
risk class IIa, according to rule 5 of the Annex IX, Directive 93/42/EEC and subsequent amendments and integrations (enforced in Italy by Leg. Decree No. 46/97 and subsequent amendments and integrations), declare under its own full liability that those devices:

- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii. come da Fascicolo Tecnico archiviato presso l'azienda;

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comply with essential requirements and dispositions of the Directive 93/42/EEC and subsequent amendments and integrations, as per the Technical Documentation filed in the Company;

- sono fabbricati in accordo al Sistema Qualità, che soddisfa i requisiti di cui all'Allegato V del sopra citato decreto legislativo, come risulta dal Certificato n. MED 26036 rilasciato in data 25/10/2006 dal KIWA CERMET ITALIA S.p.A., Via Cadriano 23, 40057 Cadriano di Granarolo (BO), Organismo Notificato n. 0476.
  are manufactured according to the Quality System which satisfies requirements of the Annex V of the above mentioned directive, as stated in the Certificate No. MED 26036 issued on 25/10/2006 by KIWA CERMET ITALIA S.p.A., Via Cadriano 23, 40057 Cadriano di Granarolo (BO), Notified Body n. 0476.

Gessate, 24/05/2021

GIMA S.p.A.
Il legale Rappresentante
The legal Representative
(Nicola Manzoni)

LARYNGOSCOPE DOCTOR SET 3 MILLER BL. 1-2-3

Code:	**34306**
Category:	**Standard laryngoscope sets**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**151933**
CND:	**Z12021003**
EAN13:	**8023279343069**

Description:

STANDARD RECHARGEABLE SETS (HANDLE + BLADES)
• Doctor set (3 blades MILLER 1, 2, 3)

Great features of the unique GIMA blades and handles
- standard 2.5 V vacuum bulb
- light ergonomic, satin finish handle to reduce glare
- Stainless Steel contacts guarantee long working life
- easy sterilization ETO or steam
- full range of Mc Intosh & Miller blades, latex free
- ISO 7376 fittings allow use of blades with existing handles
- set is packaged in an anti-shock case and in cardboard box
- 2.5 V handles work with both alkaline batteries or rechargeable batteries
- good light transmission of 3,500 LUX with 2.5 V handles
- autoclavable up to 134° for 5 minutes (approx. 2,000 times)
- non magnetic blades

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DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

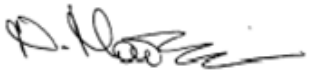
Medical Device (Trade Name and description)	**Code**	**Basic UDI-DI code**
LARYNGOSCOPE DOCTOR SET 3 MILLER BL. 1-2-3	34306	8023279Z120210030000000MQ

Risk class I (Not sterile), according to the Rule 13 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;
- comply with directive 2011/65/EU (and subsequent amendments and integrations) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Gessate, 5/28/2021

GIMA S.p.A.
The legal Representative
(Nicola Manzoni)



CPR MASK - pocket resuscitator

Code:	**34218**
Category:	**Mouth to mouth resuscitaton masks**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**2099169**
CND:	**R03010105**
EAN13:	**8023279342185**

Description:

The CPR pocket mask is a non-invasive, latex free mask with inflatable cuff and an integral non-rebreathing valve and efficient filter to prevent direct mouth contact with the patient's face when providing mouth-to-mouth resuscitation.
It can be used on adult, child and infant.
Supplied in a compact plastic box with a corrugated tube for an easier use.

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DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

Medical Device (Trade Name and description)	Code	Basic UDI-DI code
CPR MASK - pocket resuscitator	34218	8023279R03010105F600000MW

Risk class I (Not sterile), according to the Rule 1 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

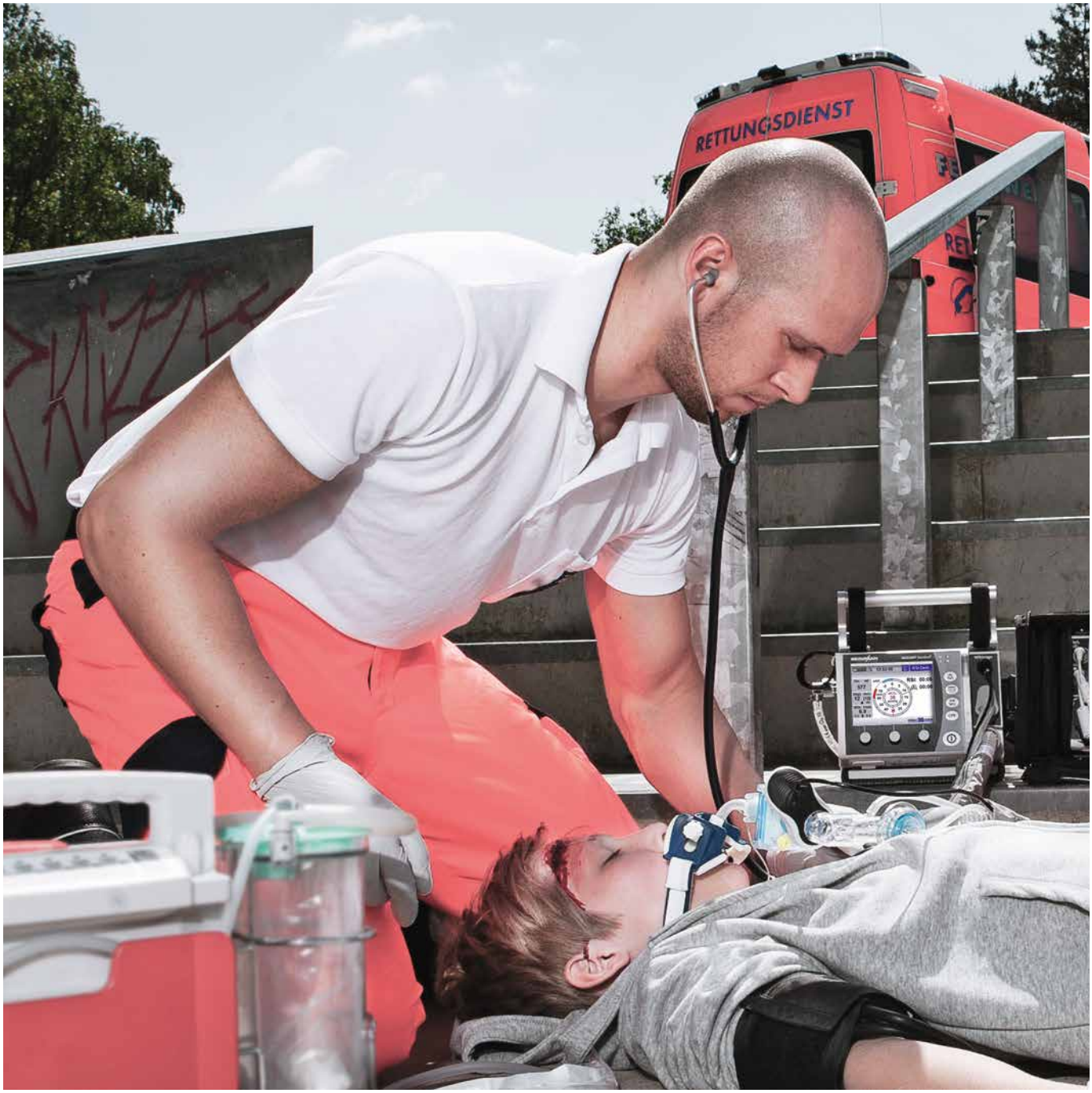
- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;

Gessate, 5/28/2021

GIMA S.p.A.
The legal Representative
(Nicola Manzoni)

MEDUMAT Standard²

A clear new perspective



MEDUMAT Standard²

Maximum safety in an emergency

In an emergency, every second counts. Every move has to be perfect, especially where respiration support is concerned, which is when prompt correct action can be a key factor in saving lives. The demands on emergency medical services are high in such situations, and easy operation of the ventilator is critical for a successful outcome. MEDUMAT Standard² is the perfect partner for just this situation. It is intuitive to operate, reliable in use and its integrated hygiene filter protects it from contamination, ultimately guaranteeing an unbeatable degree of safety for the patient, the user and the device itself!

See for yourself: You can see more

MEDUMAT Standard² provides a completely new perspective on modern emergency and transport ventilation. It clearly displays all the important respiratory parameters and an overview of ventilation curves is an additional option. The familiar operation – patient selection, for example – allows intuitive handling, whilst the initiation of ventilation by inputting height ensures that ventilation starts simply and in compliance with guidelines. Controls and symbols are clearly arranged to provide an overview, with effective audible and visual alarms as further features to ensure maximum patient safety.

Your benefits at a glance

- Quick and easy access to the right ventilation by inputting height or via emergency mode for adults, children and infants
- CPR mode for guideline-compliant cardiopulmonary resuscitation
- RSI mode for reliable support during induction of anesthesia
- CPAP mode with optional ASB pressure support for non-invasive respiratory treatment in a prehospital setting
- Hygiene filter provides protection from contamination

New outlook: More functions for emergency medical personnel

MEDUMAT Standard² also provides a much better outlook in terms of flexibility. Integration of robust flow measurement close to the patient, with sidestream capnography and a curve display, delivers optimal patient monitoring. **The optional modes available allow** MEDUMAT Standard² to be customized for individual circumstances and users. In addition to IPPV, the modes also encompass CPR (for cardiopulmonary resuscitation), RSI (for support during induction of anesthesia), Demand and CPAP (optionally with ASB). Volume-controlled modes SIMV, S-IPPV and Inhalation, together with pressure-controlled modes PCV, aPCV, BiLevel + ASB and PRVC + ASB, can furthermore still be enabled as options along with CO_2 monitoring mode. All settings are based on current specifications, e.g. resuscitation in accordance with ERC Guidelines. However, they can also be customized on request.

Optional functions

- Sidestream capnography for ideal monitoring of ventilation treatment
- Flow measurement for improved monitoring during ventilation, resuscitation or induction of anesthesia (MVe, Vte, ftotal, fspont, Vleak), curve display
- Pressure-controlled ventilation modes for more differentiated ventilation therapy
- **Bluetooth®** data transmission for digital documentation of ventilation data
- Innovative resuscitation ventilation with CCSV mode

More Than Pure Emergency Ventilation

Transport ventilation "light"

MEDUMAT Standard² is suitable not only for emergency ventilation, but also for optimal care during transport of patients already being ventilated. It is the smallest and lightest transport ventilator in its class. Equipped with pressure-controlled ventilation modes and monitoring options such as display of pressure, flow and CO_2 curves and display of major ventilation parameters, MEDUMAT Standard² is your compact partner for ground and air rescue services.

Your benefits at a glance

- Low weight of 2.5 kg makes it suitable for ground and air rescue services
- Battery life of 10 hours ensures a high level of mobility
- Simple, intuitive operation via flat menu structures
- Optimum setting and monitoring of ventilation using the Flow measurement + ASB, Capnography and Pressure-controlled ventilation modes options
- Customization and standardization of the device, e.g., by preconfiguring ventilation parameters
- Digital documentation of ventilation data using the Bluetooth® data transmission option

Digitally en route – with the Bluetooth® data transmission option

Documentation is just as important as rescue and safe transport. Bluetooth® technology makes it possible to transmit ventilation parameters, settings and trend data wirelessly and quickly to digital documentation systems - to the Medical Pad from Tech2go, for example. This facilitates seamless, paperless documentation.

CPAP Mode

Non-invasive ventilation

Proven CPAP mode allows the patient to breathe spontaneously at an elevated pressure level, e.g., during treatment of cardiac pulmonary edema**. With MEDUMAT Standard², CPAP pressure can be fine-tuned at any time. The user also has the option of activating ASB pressure support with a settable trigger. Optional volume and CO_2 monitoring ensure comprehensive monitoring, even during non-invasive ventilation.

Any leakage at the mask is detected and compensated for by the device. All ventilation parameters can be adjusted via the monitor during ventilation.

Flow measurement + ASB option

- Monitoring of expiratory tidal and minute volume as well as of respiratory rate
- Pressure support in CPAP and SIMV modes provides optimal assistance for non-invasive ventilation
- Inspiration and expiration trigger can be set individually

FlowCheck sensor

- Particularly robust during use and hygienic reprocessing
- Available in disposable or reusable variants
- Unique chip technology ensures maximum precision
- Minimal dead space of just 9 ml makes it suitable for children and adults

Your benefits at a glance

- CPAP therapy improves patient outcome in cases of acute respiratory insufficiency**
- ASB pressure support for more differentiated non-invasive ventilation available as an option
- Lower oxygen consumption compared to flow CPAP systems
- Apnea ventilation provides high level of safety

**Sources:

Bakke SA et al.: Continuous positive airway pressure and noninvasive ventilation in prehospital treatment of patients with acute respiratory failure. A systematic review of controlled studies. Scand J Trauma Resusc Emerg Med 22: 69, 2014.

Goodacre S et al.: Prehospital noninvasive ventilation for acute respiratory failure: systematic review, network meta-analysis and individual patient data meta-analysis. Acad Emerg Med 21: 960-970, 2014.

Williams, B. et al.: When pressure is positive: a literature review of the prehospital use of continuous positive airway pressure. In: Prehospital and disaster medicine 28 (2013), No. 1, pp. 52-60

Deutsche Gesellschaft für Pneumologie und Beatmungsmedizin e.V. (ed.): S3–Leitlinie: Nichtinvasive Beatmung als Therapie der akuten respiratorischen Insuffizienz [S3 Guidelines: non-invasive ventilation as treatment of acute respiratory insufficiency]. Hannover, 2008

Thompson, J. et al.: Out-of-hospital continuous positive airway pressure ventilation versus usual care in acute respiratory failure: a randomized controlled trial. In: Annals of emergency medicine 52 (2008), No. 3, pp. 232-241

CPR Mode

Cardiopulmonary resuscitation

MEDUMAT Standard² guides you reliably through cardiopulmonary resuscitation. Following a quick start using the CPR button and selection of the patient group, ventilation starts automatically using preconfigured settings. Ventilation can be controlled manually by the MEDUtrigger close to the patient. Following intubation, it is then possible to switch easily to continuous ventilation. All the critical information, e.g., when the patient was last ventilated or duration of CPR so far, is visible on the monitor. Optional display of $etCO_2$ in the form of curves or trends provides emergency medical services with an important parameter for the quality of resuscitation and intubation.

CCSV – the ventilation mode that supports the heart

With Chest Compression Synchronized Ventilation (CCSV), WEINMANN Emergency has developed a ventilation mode specifically designed for resuscitation. CCSV applies a pressure-controlled mechanical breath synchronized with each chest compression. This revolutionary method is proven to improve gas exchange and hemodynamics.

Your benefits at a glance

- Increases patient safety compared to bag/mask ventilation
- Mask held securely in place with two hands, as breaths are triggered close to the patient by MEDUtrigger
- Individual activation/deactivation of alarms (and consequently fewer irritating alarms during CPR)
- Individual configuration options for CPR mode for greater flexibility

Optional functions

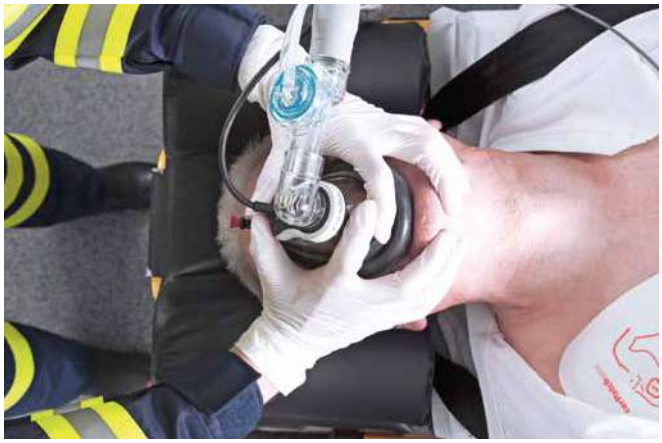
- Innovative resuscitation ventilation with CCSV mode
- Capnography for checking tube position and improved detection of ROSC
- $etCO_2$ trend display to support detection of ROSC

Press CPR button to activate CPR mode

- CPR mode is activated at the touch of a button
- Ensures use within seconds
- Clear setup for successful CPR
- Optional: CCSV ventilation easily integrated in CPR mode

Manual ventilation with MEDUtrigger and Double-C grip

- Two hands free for ventilation and thus complete control of mask with Double-C grip
- Simultaneously simple and ergonomic manual triggering of mechanical breaths using the thumbs
- Safe use due to fixed tidal volume setting and pressure limit



Continuous ventilation

- $etCO_2$ display provides a reliable check of tube position
- Preset patient height automatically sets tidal volume and ventilation rate
- Ventilation can be paused to prevent artifacts during cardiac rhythm analysis

Innovative ventilation for resuscitation – CCSV mode

- Simplified operation for resuscitation: Display reduced to the essentials
- Compatible with automatic chest compression devices
- Compression rate and hands-off time displayed

RSI Mode

Reliable support for induction of anesthesia

MEDUMAT Standard² reliably supports every treatment step in Rapid Sequence Induction mode. The patient is first preoxygenated via the DEMAND function. The operator can see the anesthesia-induced apnea directly on the monitor. MEDUtrigger close to the patient allows temporary manual ventilation - to enable the position of airway access to be checked, for example. A switch to controlled ventilation can then be made at any time using all the preset parameters, with the adjustable pressure limit guaranteeing patient safety in every situation. CO_2 monitoring lets the user check the position of the tube, a feature that further enhances patient safety.

Preoxygenation

- Supply of 100 % oxygen for the patient who is still breathing spontaneously
- Reliable monitoring of spontaneous breathing by means of volume and frequency monitoring (optional)
- Reliable alarms for prolonged apneic phase

Manual triggering of mechanical breaths with MEDUtrigger

- In an emergency, the patient can be ventilated manually using MEDUtrigger and the Double-C grip

Position check of tube

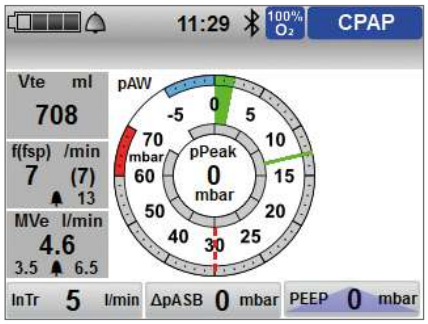
- Following successful intubation, the user can check the position of airway access using MEDUtrigger and optional capnography
- Following a position check, the device can be switched to continuous ventilation (IPPV or BiLevel + ASB) at the touch of a button

Your benefits at a glance

- RSI mode provides optimal process support of prehospital induction of anesthesia
- Pressure gauge to visualize (uninterrupted) spontaneous respiration
- Adjustable pressure limit delivers increased safety
- Optional: Improved monitoring of spontaneous breathing via volume monitoring
- MEDUtrigger and optional capnography can be used to check tube position reliably by means of auscultation
- Option of switching directly to continuous ventilation improves ergonomics

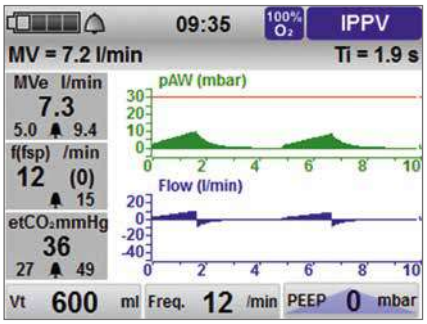
More Freedom with More Options

MEDUMAT Standard² now offers an even better outlook in terms of flexibility. The device can be individually configured to suit your needs and can thus be used for a wide range of applications.



Flow measurement + ASB option

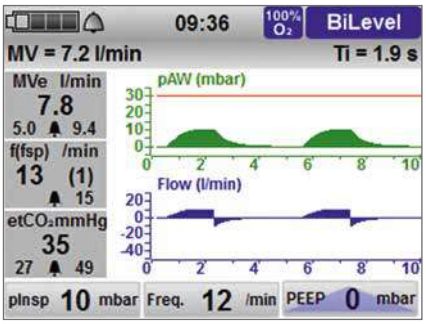
- Monitoring of expiratory tidal and minute volume, in addition to respiratory rate
- Pressure support in CPAP and SIMV modes to provide ideal assistance in non-invasive ventilation
- Inspiration and expiration trigger can be set individually



Curve display option

Condition:
Flow measurement + ASB option is installed!

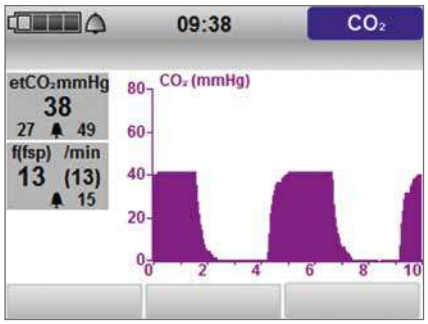
- Pressure and flow curves displayed for clear monitoring



Pressure-controlled ventilation modes option

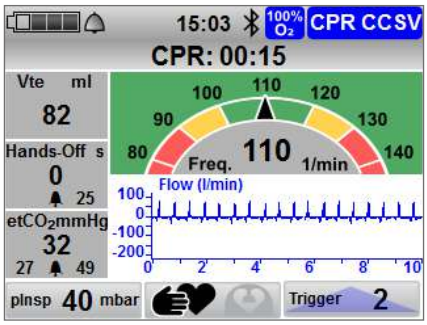
Condition:
Flow measurement + ASB option and Curve display option are installed!

- Improved transport of ventilated patients using the PCV, aPCV, BiLevel + ASB and PRVC + ASB ventilation modes
- Pressure and flow curve display for clear monitoring



Capnography option

- End-tidal CO_2 displayed in the form of a measured value, a curve and as a trend over an extended period
- Improved monitoring of ventilation treatment and support during CPR and RSI
- CO_2 measurement even with ventilation deactivated



CCSV mode option

Condition: Flow measurement + ASB option is installed

- Ventilation mode specifically for resuscitation
- For optimal ventilation synchronized with each chest compression

Bluetooth® data transmission option

- Wireless transmission of ventilation data to an external documentation system
- Simplified documentation

Other options: • SIMV mode • S-IPPV mode • Inhalation mode

Intuitive Operation for Maximum Safety

1. Optimal screen arrangement
for a perfect view of all measurements and settings

2. Accessories connection

for MEDUtrigger and connection cable to the FlowCheck sensor **accessible from the front**

3. Hygiene filter
protects the device from viral and bacterial contamination

4. Data memory and updates
Device configuration and software updates can be transmitted with the aid of the SD memory card itself

5. User-oriented operation
Rapidly-operated navigation buttons are simple and quick to use

6. Connection for ventilation hose
connects the device to the patient circuit

7. Connection for measuring tube system
measures pressure and CO_2 and manages PEEP

8. Li-Ion removable rechargeable battery
with a life of up to 10 hours

"Need to change the hygiene filter? It couldn't be simpler!"

The hygiene filter is a 1:1 fit in the dust filter opening of your device.

Accessories and Replacement Parts

- 2 m reusable patient circuit WM 28860
- 2 m disposable patient circuit WM 28865
- 2 m disposable patient circuit for adults and children WM 28867
- 2 m reusable patient circuit with flow measurement WM 29197
- 2 m disposable patient circuit with flow measurement WM 29195
- 2 m disposable patient circuit for adults and children, with flow measurement WM 29194
- 2 m reusable patient circuit with CO_2 measurement WM 28905
- 2 m disposable patient circuit with CO_2 measurement WM 28907
- 2 m disposable patient circuit for adults and children, with CO_2 measurement WM 28904

1. 2 m reusable patient circuit with flow measurement, with CO_2 measurement WM 29190

2. 2 m disposable patient circuit with flow measurement, with CO_2 measurement WM 29192

3. 2 m disposable patient circuit for adults and children, with flow measurement, with CO_2 measurement WM 29199

4. Reusable FlowCheck sensor WM 28835

- Set of 5 reusable FlowCheck sensors WM 17850

5. $etCO_2/O_2$ nasal cannula WM 1928

6. 2 m MEDUtrigger WM 28992

7. 2 m connection cable to FlowCheck sensor with MEDUtrigger WM 32508

8. 2 m connection cable to FlowCheck sensor without MEDUtrigger WM 32506

9. Hygiene filter WM 28740

- Set of 5 hygiene filters WM 17865
- MAG adapter for power supply WM 28979

10. Battery charging station WM 45190

- Power supply unit and charger WM 28937

11. Battery WM 45045

- Adapter for connection of oxygen inhalation WM 28263
- SD card WM 29791

12. Respiratory system filter WM 22162

- EasyLung for WEINMANN Emergency WM 28625

Examples of Configuration Options

1 Select your device, e.g.:

MEDUMAT Standard² with CO_2 measurement (WM 29500)

MEDUMAT Standard² without CO_2 measurement (WM 29300)

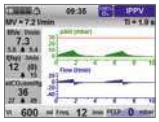
\+ Can be combined with monitor/ defibrillator system

MEDUCORE Standard

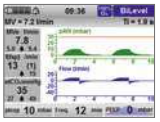
MEDUCORE Standard²

2 Select your software options, e.g.:

Flow measurement (WM 28959)



Curve display (WM 28963)



Pressure-controlled ventilation modes (WM 28970)

CCSV mode (WM 28940)

Bluetooth® data transmission (WM 28945)

- SIMV mode (WM 28916)
- S-IPPV mode (WM 28915)
- Inhalation mode (WM 28920)

3 Select your preferred accessories, e.g.:

Reusable / disposable patient circuits

Hygiene filter

NIV / CPAP masks

Respiratory system filter

4 Select your portable system with or without oxygen cylinder, e.g.:

LIFE-BASE light XS portable system

LIFE-BASE 1 NG XS portable system

LIFE-BASE 3 NG portable system

5 Select pressure reducer and oxygen cylinder, e.g.:

OXYWAY pressure reducer

Steel or aluminum cylinder

✓ Your individual configuration

MEDUMAT Standard² on LIFE-BASE light XS portable system

MEDUMAT Standard² on LIFE-BASE 1 NG XS portable system

MEDUMAT Standard² with MEDUCORE Standard² on LIFE-BASE 3 NG

Service Directly from the Manufacturer

Remote diagnosis (telesupport) in the event of a fault Safety and reliability day after day

With the fast and simple function check, you can assure yourself at any time that your device is trouble-free and ready for use. In less than 30 seconds, MEDUMAT Standard² performs the automatic function check and provides the user with a status report. If a device malfunction does ever occur, its cause may not be immediately apparent. For reporting purposes, MEDUMAT Standard² lets you save the service files from the device to an SD card and e-mail them to WEINMANN Emergency. Ideally, these data alone will be sufficient for our service specialists to resolve the fault with you via telesupport. Should this not be the case, we will take a closer look at your device and, if necessary, you will be provided with a replacement device to cover this down time.

Perform software updates yourself – Your benefits as the operator:

- Always up-to-date with the latest software
- You decide when to update – no appointment pressure, no waiting
- Remain ready for use – no need to ship device for update
- You decide who makes the update at your site - password-protected operator menus make this possible
- No risk – performing the update is simple and safe

Active support of your quality management and documentation processes

Important information is saved automatically and can be exported to the SD card quickly and easily. Data included:

- Up to 6,000 function checks, including many details
- Software update history as a documentation sheet
- Error-free standardization: Customized device configurations can be transferred from one device to another by SD card

Service data: MEDUMAT Standard²

Manufacturer's warranty	2 years
Safety check interval	Every 2 years
Servicing interval	Every 2 years
COMFORT Plus service package with fixed annual fees available	✓
Automatic function check with clear summary	✓
Duration of function check	Approx. 25 seconds
Software update can be performed by operator/user	✓
User training without O_2 consumption (free simulation software in the device/on PC)	✓
Password-protected operator menu	✓
Removable rechargeable battery system(1)	✓
Battery status	Display also on battery itself
Telesupport	✓
External charging base for removable battery	Available as an option
Service reminder in device display	E.g., of scheduled safety check / servicing

(1) You can use the removable rechargeable battery for both MEDUMAT Standard² and MEDUCORE Standard to support your logistical processes and simplify device handling during use.

Never miss a safety check or service interval again

MEDUMAT Standard² gives you reliable help with the planning of required servicing. Every device reminds you in good time of due servicing/safety check dates. At the end of the function check, the device tells the user the exact date of upcoming servicing/safety checks. If the recommended interval is exceeded, MEDUMAT Standard² also displays a small spanner symbol on the start-up screen. MEDUMAT Standard² uses these reminders to support you in your responsibility as device operator.

Manufacturer Service

Hotline: +49 40 88 18 96 122

Technical Data

MEDUMAT Standard²

Device dimensions	W: 206 mm x H: 137 mm x D: 130 mm
Weight, incl. battery	Approx. 2.5 kg
Product class according to Directive 93/42/EEC	IIb
Operating conditions	• Temperature range: -18 °C to +50 °C • Humidity: 0 % rh to 95 % rh, no condensation • Air pressure: 540 hPa to 1,100 hPa • Altitude above MSL: up to 5,000 m
Rechargeable battery	• Operating time: up to 10 hrs (depending on device and options) • Charging time (0 % - 95 %): 3.5 h
Display	TFT color display 5″
Data storage	Internal and on SD card
Ventilation modes	• Volume-controlled: IPPV, CPR, RSI, SIMV (with SIMV mode option), SIMV + ASB (with SIMV mode and Flow measurement + ASB options), S-IPPV (with S-IPPV mode option), Inhalation (with Inhalation mode option) • Pressure-controlled: PCV, aPCV, BiLevel + ASB, PRVC + ASB (with pressure-controlled ventilation modes option), CCSV (with Flow measurement + ASB option and CCSV mode option) • Spontaneous breathing: CPAP, CPAP + ASB (with Flow measurement + ASB option)
Operating gas	Medical-grade oxygen or concentrator oxygen (93 % O_2)
Operating pressure range	2.7 bar to 6 bar
Monitoring	• Displayed measured values: pPeak, pPlat, pMean, Vte, MVe, f, fsp, Vleak (with Flow measurement + ASB option), etCO_2 (with Capnography option) • Curves: Airway pressure (with Curve display option or Capnography option), Flow (with Curve display option), CO_2 (with Capnography option), etCO_2 trend (with Capnography option) • Gauge: Pressure gauge
Maximum outlet flow	80 l/min at inlet pressure of 4.5 bar in Air Mix and in No Air Mix operation
Tidal volume	50 ml to 2,000 ml
Ventilation rate	5 min^{-1} to 50 min^{-1}
Inspiration pressure	3 mbar to 60 mbar (with Pressure-controlled ventilation modes option)
ASB pressure support	0 mbar to 30 mbar (with Flow measurement + ASB option)
PEEP	0 mbar to 30 mbar
Pressure limit (Pmax)	10 mbar to 65 mbar
Inspiration trigger	1 l/min to 15 l/min (with Flow measurement + ASB option)
Expiration trigger	5 % to 80 % flow max. (with Flow measurement + ASB option)
I:E	1:4 – 4:1
Pressure ramp	Steep, medium, flat (with Flow measurement + ASB option)
Standards applied	EN 60601-1, EN 1789, EN 794-3, ISO 10651-3, RTCA DO-160 G, MIL STD 810 G

CE 0197

Zertifiziertes QM-System nach EG-Richtlinie 93/42/EWG, Anh. II (EN ISO 9001:2008/EN ISO 13485)

We reserve the right to make changes to the technical specifications without notice.

Made in Germany

visit our website

follow us on facebook

watch our videos on YouTube

connect with us on LinkedIn

Simply Professional

WEINMANN Emergency is a family-owned, internationally active medical technology company. With our mobile system solutions for emergency, transport and disaster medicine, we set standards for saving human lives. In close collaboration with professional users in emergency medical services, hospitals and military medical corps, we develop innovative medical products for ventilation and defibrillation. For more than 100 years we have offered our customers a high degree of reliability, extensive experience and quality made in Germany.

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Simply Professional Made in Germany WEINMANN-Emergency.com

EG-Konformitätserklärung für Medizinprodukte

Wir, der Hersteller, erklären in alleiniger Verantwortung, dass das unten aufgeführte Produkt den einschlägigen Bestimmungen der nachstehenden Richtlinien entspricht.

Hersteller:	WEINMANN Emergency Medical Technology GmbH + Co. KG Frohbösestraße 12, 22525 Hamburg GERMANY
Produktbezeichnung:	**Beatmungsgerät**
Produktname / Modell:	**MEDUMAT Standard^2**
Richtlinie:	Richtlinie 93/42/EWG über Medizinprodukte (gemäß Anhang II ohne (4))
Klassifizierung:	IIb
Kennzeichnung:	TÜV-Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Deutschland **CE 0197**

Diese EG-Konformitätserklärung ist gültig ab dem Datum der Unterzeichnung bis zur Ausstellung einer revidierten EG-Konformitätserklärung aufgrund der Ausstellung eines neuen Richtlinienzertifikats.

Hamburg, den 20.04.2020

André Schulte
Sprecher der Geschäftsführung

WM 74460e 08/2020 DE

EC Declaration of Conformity on Medical Devices

We, the manufacturer, declare in sole responsibility that the product mentioned below is in conformity with the respective regulations of the following guideline.

Manufacturer:	WEINMANN Emergency Medical Technology GmbH + Co. KG Frohbösestraße 12, 22525 Hamburg GERMANY
Product description:	**Ventilator**
Product name / Model:	**MEDUMAT Standard^2**
Guideline:	Medical Device Directive 93/42/EEC (according to Annex II excluding (4))
Classification:	IIb
Marking:	TÜV-Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Germany CE 0197

This EC declaration of conformity is valid from the date of signature until a revised EC declaration of conformity is issued as a result of a new directive certificate being issued.

Hamburg, 20/04/2020

André Schulte
Chief Executive Officer

WM 74460e 08/2020 EN

Déclaration CE de conformité pour dispositifs médicaux

Nous, le constructeur, déclarons en seule responsabilité que le produit mentionné ci-dessous répond aux dispositions respectives de la directive ci-après.

Constructeur :	WEINMANN Emergency Medical Technology GmbH + Co. KG Frohbösestraße 12, 22525 Hamburg GERMANY
Désignation du produit :	**Ventilateur**
Nom du produit / modèle :	**MEDUMAT Standard^2**
Directive :	Directive européenne 93/42/CEE relative aux dispositifs médicaux (conformément à l'annexe II sans [4])
Classification :	IIb
Marquage :	TÜV-Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Allemagne CE 0197

La présente déclaration CE de conformité est valide à compter de la date de sa signature et jusqu'à présentation d'une déclaration de conformité CE révisée suite à l'établissement d'un nouveau certificat.

Hambourg, le 20/04/2020

André Schulte
Porte-parole de la direction

WM 74460e 08/2020 FR

Declaración CE de conformidad para productos sanitarios

Nosotros, el fabricante, declaramos bajo nuestra responsabilidad exclusiva que el producto citado posteriormente cumple las disposiciones pertinentes de las siguientes directivas.

Fabricante:	WEINMANN Emergency Medical Technology GmbH + Co. KG Frohbösestraße 12, 22525 Hamburg GERMANY
Denominación de producto:	**Dispositivo de respiración artificial**
Nombre del producto/modelo:	**MEDUMAT Standard^2**
Directiva:	Directiva 93/42/CEE relativa a los productos sanitarios (según el anexo II sin (4))
Classificación:	IIb
Identificación:	TÜV-Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Alemania

CE 0197

Esta declaración CE de conformidad es válida a partir de la fecha de la firma y hasta la expedición de una declaración CE de conformidad revisada debido a la expedición de un nuevo certificado de directiva.

Hamburgo, a 20.04.2020

André Schulte
Portavoz de la gerencia

WM 74460e 08/2020 ES

The Mediwet humidifiers are developed for oxygen therapy at hospital or at home. This type of equipment is indispensible to prevent dehydration of the mucous membranes when inhaling oxygen during an extended period of time, or at large flows. It is intended to be connected to the outlet of a wall flowmeter, a regulator flowmeter, or an oxygen concentrator.

Humidifiers
Mediwet

EDITION 1/2009

The reusable humidifier is ergonomic, comfortable, economic, and easy to maintain:

- Reduced dimensions and weight.
- Silent thanks to a high performance diffuser.
- All components, except the diffuser, are reusable for minimum 20 autoclave cycles.
- Improved adaptation to the needs and possibilities of the user with two autoclave possibilities, depending on the material.
- Fast to assemble/disassemble.

Gas Control Equipment

MEDIWET 2 HUMIDIFIER

Art. No.	Denomination
K293498	Mediwet 2 134 °C inlet connection M12x1,25F
K294402	Mediwet 2 134 °C inlet connection UNF 9/16 F
K293491	Mediwet 2 121 °C inlet connection M12x1,25 F
K294401	Mediwet 2 121 °C inlet connection UNF 9/16 F
K294416	Mediwet 2 121 °C inlet connection G3/8F

Spare Parts

Art. No.	Denomination
K301062	Jar 134 °C
K301059	Jar 121 °C
K301063	Lid 134 °C connection M12x1,25
K301060	Lid 121 °C connection M12x1,25
K301064	Lid 134 °C connection 9/16
K301061	Lid 121 °C connection 9/16
K301078	Lid 134 °C connection G3/8
K301079	Lid 121 °C connection G3/8
K294404	Inlet connection gasket M12x1,25, 10 pcs
K294407	Inlet connection gasket 9/16, 10 pcs
K294433	Inlet connection gasket G3/8, 10 pcs
K294409	Bottle gasket 134 °C, 10 pcs
K294408	Bottle gasket 121 °C, 10 pcs

Consumables

Art. No.	Denomination
K294415	Diffuser, 10 pcs
M401006	Silicone hose 1 m
K294486	Silicone tube, 10 pcs
K294434	Complete diffuser (tube 13 cm and diffuser, 10 pcs)

MEDIWET HUMIDIFIER

Art. No.	Denomination
K292247	Mediwet 200 ml
K292254	Mediwet 500 ml

Spare Parts

Art. No.	Denomination
K308031	Inlet gasket
K308035	Jar gasket
K301047	Lid
K291576	Diffuser tube
K291582	Jar 200 ml
K301091	Jar 500 ml

K293498

K293491

Technical Data - MEDIWET 2 HUMIDIFIER

Contents:	Only sterile water
Dimensions:	Height 190 x 67 Width (incl hose nipple) x 57Ø mm
Weight:	Polycarbonate version 75 g
	Polysulphone version 115 g
Capacity:	200 ml of water
Consumption:	8 ml of water per hour at a as flow of 10 l/min at 20 °C
Material:	Jar autoclavable at 121 °C: polycarbonate
	Jar autoclavable at 134 °C: polysulphone
	Lid and outlet hose nipple: polypropylene
	Inlet nut: Chromed brass
	Diffuser: Polyethylene
	Hose, flat gasket: Silicone
	Toric gasket: Ethylene propylene
Outlet connection	Tapered hose nipple for hose 6x9 mm (recommended length 2 m)
Cleaning:	Water, non abrasive detergent. Never use solvents.
Disinfection:	An alcoholic solution, or other solution compatible with the material according to the disinfectant manufacturer.
Autoclave:	Polycarbonate version 121 °C for 30 minutes
	Polysulphone version 134 °C for 18 minutes
Special case:	Diffuser: exchange at every cleaning - do not sterilise!
	Silicone tube: autoclave at 121 °C (if cold disinfection please exchange!)
Maintenance	Check that the humidifier is whole and air tight before use. Monthly exchange of gaskets is recommended. Exchange the diffuser when its microperforations no longer exist.
Durability	Minimum 20 autoclave cycles under the condition that all instructions accompanying the product are adhered.

Technical Data - MEDIWET HUMIDIFIER

Contents:	Only sterile water
Dimensions:	200 ml: Height 115 x Width 83 (incl hose nipple) x 57Ø mm
	500 ml: Height 210 x Width 89 (incl hose nipple) x 70Ø mm
Weight:	200 ml: 185 g
	500 ml: 190 g
Material:	Jar and lid: polycarbonate
	Connections: chromed brass

Recycling

The product shall be recycled according to local regulations.

K292254

K292247

Gas Control Equipment
GCE Norden AB , Flygfältsvägen 1, Box 21044, SE-200 21 Malmö
Telephone: +46 (0) 40 38 83 00, Fax. +46 (0) 40 38 83 50
http://www.gcegroup.com

Product Description 700 325 736 090421em.

Gas Control Equipment

Intrebati

Pentru mai multe detalii despre acest produs, contactati echipa de vanzari din regiune.

Cautare Produs

Apasati pentru a mari

Client Inregistrat?
Suport Tehnic si post-vanzare

MEDISELECT® II

Cod produs: 3211

Vizualizati mai multe imagini

Regulator de presiune pentru utilizarea cu butelii de gaze medicale prevazute cu robinet de butelie medical.

- Regulator cu selector de debit. Manometru de presiune rotativ care permite intotdeauna o citire confortabila
- Iesirea cu posibilitatea rotatiei la 360° – asigura o orientare mai buna catre canula nazala sau masca de oxigen inspre pacient, prevenind indoirea sau rasucirea furtunului
- Dispozitiv inovator de setare a debitului cu o curgere continua intre setari. In cazul putin probabil al deteriorarii mecanismului zimtat, pacientul va fi aprovizionat in continuare cu gaz medical.
- Citirea setarilor de debit laterala si frontala
- Numarul marit de orificii in discul de debit creste numarul optiunilor de tratament. Posibilitatea setarii la
  25 l/min, spre deosebire de variant traditionala cu 15 l/min variant, permite folosirea in resuscitari.
- Cei 7 l/min aditionali sunt destinati pentru nebulizare.

DATE TEHNICE

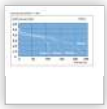
Gaz:	O_2, Aer, N_2O, CO_2, O_2/N_2O
Presiune intrare:	Pana la 300 bar
Presiune iesire:	3,6 - 5,5 bar
Gama de presiune*:	
de la 0 la 2 l/min:	0/ 0,1 / 0,2 / 0,3 / 0,4 / 0,5 / 0,6 / 0,7 / 0,8 / 1 / 1,5 / 2
de la 0 la 6 l/min:	0/ 0,25 / 0,5 / 0,75 / 1 / 1,5 / 2 / 2,5 / 3 / 4 / 5 / 6
de la 0 la 25 l/min:	0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 9 / 12 / 15 / 25
Conexiune intrare:	In concordanta cu standardele nationale
Conexiune iesire:	9/16 UNF, M12×1,25, G3/8, G1/4 + stut furtun
Materialul corpului:	Alama nichelata
Robinetul de control:	Poliamida
Garnituri:	EPDM
Filtru:	Bronz sinterizat
Aparatoarea manometrului:	TPE (elastomer termoplastic)
Reglementari:	In conformitate cu Directiva Dispozitivelor Medicale 93/42/EEC In conformitate cu EN ISO 10524-1 In conformitate cu EN 1789 Produs in concordanta cu EN ISO 9001 si EN ISO 13485
Clasificare:	Clasa IIb

* Debitele sunt valabile la 23°C si 101,3 kPa

Informatii tehnice

Sus

Descarcati informatiile tehnice




Descarcarile

Sus

Informatii suplimentare pentru acest produs

Traducere din limba engleză

Umidificatoarele Mediwet au fost dezvoltate pentru terapia cu oxigen în spital sau la domiciliu. Acest tip de echipament este indispensabil pentru a preveni deshidratarea membranelor mucoase atunci când se inhalează oxigen de-a lungul unei perioade de tip prelungite sau în debite mari. Acesta trebuie conectat la priza unui debitmetru de perete, un debitmetru cu regulator sau un concentrator de oxigen.

Umidificatoare Mediwet

EDIŢIA 1/2009

Umidificatorul reutilizabil este ergonomic, confortabil, economic şi uşor de întreţinut:

- Dimensiuni şi greutate reduse.
- Silenţios datorită difuzorului de înaltă performanţă.
- Toate componentele, cu excepţia difuzorului, pot fi reutilizate timp de minimum 20 de cicluri în autoclavă.
- Adaptare îmbunătăţită la nevoile şi posibilităţile utilizatorului cu două posibilităţi de autoclavă, în funcţie de material.
- Uşor de asamblat/dezasamblat.

Traducere din limba engleză

UMIDIFICATOR MEDIWET 2

Nr. art.	Denumire
K293498	Conexiune internă 134ºC Mediwet 2 M12x1,25F
K294402	Conexiune internă 134ºC Mediwet 2 UNF 9/16 F
K293491	Conexiune internă 121ºC Mediwet 2 M12x1,25 F
K294401	Conexiune internă 121ºC Mediwet 2 UNF 9/16 F
K294416	Conexiune internă 121ºC Mediwet 2 G3/8F

Piese de schimb

Nr. art.	Denumire
K301062	Borcan 134ºC
K301059	Borcan 121ºC
K301063	Capac 134ºC conexiune M12x1,25
K301060	Capac 121ºC conexiune M12x1,25
K301064	Capac 134ºC conexiune 9/16
K301061	Capac 121ºC conexiune 9/16
K301078	Capac 134ºC conexiune G3/8
K301079	Capac 121ºC conexiune G3/8
K294404	Manşon conexiune internă M12x1,25, 10 buc.
K294407	Manşon conexiune internă 9/16, 10 buc.
K294433	Manşon conexiune internă G3/8,10 buc.
K294409	Manşon sticlă 134ºC, 10 buc.
K294408	Manşon sticlă 121ºC, 10 buc.

Consumabile

Nr. art.	Denumire
K294415	Difuzor, 10 buc.
M401006	Furtun din silicon 1 m
K294486	Tub din silicon, 10 buc.
K294434	Difuzor complet (tub 13 cm şi difuzor, 10 buc.)

UMIDIFICATOR MEDIWET

Nr. art.	Denumire K292247
	Mediwet 200 ml
K292254	Mediwet 500 ml

Piese de schimb

Nr. art.	Denumire
K308031	Manşon intern
K308035	Manşon borcan
K301047	Capac
K291576	Tub difuzor
K291582	Borcan 200 ml
K301091	Borcan 500 ml

K293498

K293491

Date tehnice - UMIDIFICATOR MEDIWET 2

Conţinut:	Numai apă sterilă
Dimensiuni:	Înălţime 190 x 67 Lăţime (incl. ştuţ furtun) x 57Ø mm
Greutate:	Versiune policarbonat 75 g Versiune polisulfon 115 g
Capacitate:	200 ml apă
Consum:	8 ml apă pe oră la un debit de 10 l/min la 20ºC
Material:	Borcan autoclavabil la 121ºC: policarbonat Borcan autoclavabil la 134ºC: polisulfon Capac şi ştuţ furtun de ieşire: polipropilenă Piuliţă de intrare: Alamă cromată Difuzor: Polietilenă Furtun, manşon plat: Silicon Manşon toric: Etilenă propilenă
Conexiune de ieşire	Ştuţ furtun conic pentru furtun 6x9 mm (lungime recomandată 2 m)
Curăţare:	Apă, detergent neabraziv. Nu utilizaţi niciodată solvenţi.
Dezinfecţie:	Soluţie cu alcool sau altă soluţie compatibilă cu materialul în conformitate cu producătorul dezinfectantului.
Autoclavă:	Versiune policarbonat versiune 121ºC timp de 30 minute Versiune polisulfon 134ºC timp de 18 min.
Cutie specială:	Difuzor: a se schimba la fiecare curăţare – a nu se steriliza! Tub de silicon: autoclavă la 121ºC (în caz de dezinfecţie la rece, vă rugăm să o schimbaţi!)
Întreţinere	Verificaţi ca umidificatorul să fie întreg şi etanş înainte de utilizare. Se recomandă schimbarea lunară a manşoanelor. Schimbaţi difuzorul atunci când nu mai există microperforaţii.
Durabilitate	Minimum 20 cicluri în autoclavă cu condiţia ca toate instrucţiunile care însoţesc produsul să fie respectate.

Date tehnice - UMIDIFICATOR MEDIWET

Conţinut:	Numai apă sterilă
Dimensiuni:	200 ml: Înălţime 115 x lăţime 83 (inclusiv ştuţ furtun) x 57Ø mm 500 ml: Înălţime 210 x lăţime 89 (inclusiv ştuţ furtun) x 70Ø mm
Greutate:	200 ml: 185 g 500 ml: 190 g
Material:	Borcan şi capac: policarbonat Conexiuni: alamă cromată

Reciclare

Produsul va fi reciclat în conformitate cu reglementările locale.

K292254

K292247

Gas Control Equipment
GCE Norden AB , Flygfältsvägen 1, Box 21044,
SE-200 21 Malmö Telefon: +46 (0) 40 38 83 00,
Fax. +46 (0) 40 38 83 50
http://www.gcegroup.com

Descrierea produsului 700 325 736 090421em.

Subsemnata **ŞTEFANA FORGACIU**, traducător autorizat de M. J. cu nr. **37629**,
certific exactitatea traducerii în limba română, cu textul înscrisului în copie, în limba engleză.

TRADUCĂTOR **ŞTEFANA FORGACIU** - *AUTORIZAT* cu nr. **37629**

EU DECLARATION OF CONFORMITY

Certificate Number:	*ZP 03-006 High Pressure Regulators_09-01*
Manufacturers Name:	GCE, s.r.o.
Manufacturers Address:	Žižkova 381, 583 01 Chotěboř, Czech Republic
SRN (Single Registration Number):	003172 RZPRO
Product Group:	*High Pressure Regulators*
Name of the Device (s):	**MEDISELECT**
Product code:	7114
Risk Classification:	IIb
GMDN code:	43438
Other used standards:	**EN ISO 10524-1:2018**
Notified Body name:	DNV Product Assurance AS
Notified Body Address:	Veritasveien 3, N-1363 Høvik, Norway
Notified Body Identification number:	2460
EC Certificate Number:	10401-2017-CE-CZS-NA-PS

Conformity assessment route:

This declaration of conformity is issued under the sole responsibility of GCE, s.r.o. We hereby declare that he medical device(s) specified above meet the provision of the Regulation MDD 93/42/EEC for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by DNV Product Assurance AS.

The product is in accordance with Annex II (excluding section 4) of the MDD 93/42/EEC and is safe for declared purpose of use under standard conditions. Any modification to the product, not authorized by us, will invalidate this declaration.

All supporting documentation is retained at the premises of the manufacturer.

Signature: Place and date (dd.mm.yyyy) of issue:

Ing. Tereza Šnapková
Digitálně podepsal Ing. Tereza Šnapková
Datum: 2021.05.28 13:47:05 +02'00'

....Chotěboř

Tereza Šnapková

Regulatory Specialist, On behalf of Tomáš Janeček, managing director.

Note: List of variants is in attachment of this docoment.

DECLARATION OF CONFORMITY

for CE – marking according to Annex II of Medical Devices Directive 93/42/EEC - 2007/47EC Amending

Manufacturer:

GCE s.r.o.
Žižkova 381
583 81 Chotěboř
CZECH REPUBLIC

The GCE, s.r.o. herewith declares under his sole responsibility that the product

Product name: Humidifiers

Model : MEDIWET

Risk Classification : IIa

is in conformity with applicable regulation

Directive : MDD 93/42/EC, Annex II – 2007/47EC Amending

Quality Assurance Standards : EN ISO 9001:2008
EN ISO 13485:2012

Procedural Standards : EN ISO 8185:2009 EN ISO 15223-1:2012
EN ISO 14971:2012 EN 1041:2008

Product is in compliance with the requirements of Annex I the MDD 93/42/EEC - 2007/47EC Amending and is safe for to be declared using in standard conditions.
Any modification to the product, not authorized by us, will invalidate this declaration.

EC Certificate No. 73547-2010-CE-CZS-NA 6.0 issued by by Det Norska Veritas, Veritasveien 1, 1322 Høvik, Norway, Notified Body No. 0434

Date of Issue: *2015-09-01*
Place of Issue : *Chotěboř*

Signature:
Quality Engineer:Vit Leszkow

GCE, s.r.o.
Žižkova 381
583 81 Chotěboř
Czech Republic

Tel. 00 420 569 661 111
Fax. 00 420 569 661 138

E-mail: gce@gcegroup.com
http:// www.gcegroup.com

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10401-2017-CE-CZS-NA-PS Rev. 0.0	**PRJC-189266-2009-PRC-CZE**	**30 MARCH 2020**

This is to certify that the quality system of:

GCE s.r.o.
Žižkova 381
583 01 Chotěboř
Czech Republic

For design, production and final product inspection/testing of:

Medical Devices for use with Medical Gases

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 1 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL-NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **10401-2017-CE-CZS-NA-PS Rev. 0.0**
Project No.: **PRJC-189266-2009-PRC-CZE**
Valid Until: **30 MARCH 2020**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0	Supersedes DNV GL (NB0434) certificate No. 73547-2010-CE-CZS-NA 7.0 following transfer of notified body function to DNV Nemko Presafe AS (NB2460)	2017-11-01

Products covered by this Certificate:

Product Description	Product Name	Class
Medical devices for use with Medical Gases	Pressure regulators integrated with cylinder valves	IIb
	Cylinder valves	
	High Pressure Regulators	
	Terminal Unit	
	Ambulance Panel	
	Central gas supply system	
	Resuscitator	
	Adjustable regulators	
Medical devices for use with Medical Gases	Flow-metering devices (Ball flow meters, Flow selectors)	IIa
	Humidifiers	
	Low pressure hoses	
	Low pressure regulators	
	Terminal Unit (for Anesthetic Gas Scavenging System)	
	Suction equipment (Suction ejectors, Vacuum regulators)	
	Demand Valve	
	Gas Switch	
	Gas Saver	

The complete list of devices is filed with the Notified Body

EC Certificate
Full Quality Assurance System

Certificate No.: **10401-2017-CE-CZS-NA-PS Rev. 0.0**
Project No.: **PRJC-189266-2009-PRC-CZE**
Valid Until: **30 MARCH 2020**

Sites covered by this certificate

Site Name	Address
GCE s.r.o.	Žižkova 381, 583 01 Chotěboř, Czech Republic

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

OB500

- Apirator de secretii OB 500
- Dispozitivul este conceput pentru autospeciale medicale si este stationar, nu portabil
- Piston aspirator fara mentenanta
- Putere de aspirare maxima: 800 mbar (80 kPa) ±10%
- Putere de aspirare nominala: 30 LPM la viteza aer liber ±10%
- Timp maxim de aspirare: 60 minute ±10%
- Grad de protectie impotriva infiltratiilor de lichide si solide: IP32d
- Functionare: 12÷15 Vdc
- Control vacuum si unitatea de reglare pot fi instalate pe perete
- Vas colectare autoclavabil OB-J FA 1000 ml cu valva supraplin si filtru de protectie inserat direct in capac, autoclavabil max de 30 ori
- Dimensiuni unitate completa: 175x175x100 mm
- Dimensiuni unitate de reglaj: 53x110x70 mm
- Greutate: max. 2 kg inclusiv cu kitul de instalare
- In conformitate cu toate reglementarile aplicate, Directiva 93/42/EEC si standardele principale de referinta

For further information and/or technical data related to the product, please refer to the Oscar Boscarol Company.

OSCAR BOSCAROL S.r.l.
Via Enzo Ferrari 29, 39100 Bolzano BZ Italy
VAT Number e Fisc. Code 01458460217
Ph. +39 0471932893 Fax. +39 0257760140
info@boscarol.it - www.boscarol.it

Quality Management

DECLARATION OF CONFORMITY – DICHIARAZIONE DI CONFORMITÁ

We, the manufacturer: *Il produttore:*	**OSCAR BOSCAROL SRL** Via E. Ferrari , 29 – 39100 BOLZANO – ITALY Tel. +39 0471 932893 – Fax. +39 0257760140 Web: www.boscarol.it - Email : info@boscarol.it Certifies EN ISO 13485:2016 – N° Q5 042208 0031 Rev. 00 Certifies UNI EN ISO 9001:2015 – N° 50 100 7289 – R.004 Emission: TÜV–SÜD Product service (CE0123) EC Certificate N° G1 042208 0032 Rev. 00
We declare under our sole responsibility that the device (name): *Dichiariamo sotto nostra responsabilità che il dispositivo (nome):*	**MEDICAL SUCTION UNIT** **ASPIRATORE MEDICALE DI SECRETI**
Type: **Tipo:** **UMDNS code:** **GMDN code:** **Boscarol code:**	**OB500 STATIONARY SUCTION UNIT** **15-016** **63643** **BSU442 – BSU462 – BSU464** **XAS0330 – XAS0331 – XAS0332 – XAS0334** **XAS0336 – XAS0338 – XAS0340**
Devices classification (MDD 93/42/EEC – Annex IX): *Classificazione dispositivo (MDD 93/42/CEE – Allegato IX):*	**Class IIa**
Meets all the provisions of the directive MDD 93/42/EEC and subsequent amendments which apply to it. *Soddisfa tutte le disposizioni della direttiva MDD 93/42/CEE e successivi emendamenti che lo riguardano.*	
Applied harmonised standards, national standards or other normative documents: *Norme armonizzate o nazionali applicate, altri documenti normative applicate:*	**ISO 10079-1** **UNI EN 1789** **IEC 60601-1** **IEC 60601-1-2** **IEC 60601-1-12** **ECE-R10**
Conformity assessment procedure: *Procedimento di valutazione della conformità:*	**MDD93/42/EEC, Annex II (Allegato II)**
Notify body: *Organismo di notifica incaricato della valutazione della conformità:*	**TÜV SÜD PRODUCT SERVICE GmbH** **CE 0123** **Ridlerstrasse 65 – 80339 München - Germany**

Bolzano, 25.08.2020

DIR/RAQ – Quality Manager
Dr. MARCHETTI BENEDETTA

DIR/CEO
BRAZZO DANIELE

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60148646 0001

Report No.: 21201240 016

Manufacturer:
WEINMANN Emergency Medical
Technology GmbH + Co. KG
Frohbösestr. 12
22525 Hamburg
Deutschland

Products: Medical devices for emergency and transport medicine

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HD 60129559 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-04-16

Date: 2020-04-16

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60148646 0001
Report No.: 21201240 016

Manufacturer:
WEINMANN Emergency Medical Technology GmbH + Co. KG
Frohbösestr. 12
22525 Hamburg
Deutschland

Products included:

Emergency and transport medicine:
- Suction pumps
- Ventilators
- Module systems
- Resuscitators
- Ventilation masks
- Patient hose systems
- Pressure reducers
- Click dial flowmeter
- Defibrillators-/Monitoring systems
- SpO2 sensors

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-04-16

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60148646 0001
Report No.: 21201240 016

Manufacturer: WEINMANN Emergency Medical Technology GmbH + Co. KG
Frohbösestr. 12
22525 Hamburg
Deutschland

Site included:

WEINMANN Emergency Medical Technology GmbH + Co. KG
Siebenstücken 14
24558 Henstedt-Ulzburg, Germany

Activities: Production

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-04-16

Dipl.-Ing. I. Munkler

ACCUVAC Lite

Putere în simplitate – Aspirarea devine formalitate

ACCUVAC Lite

Putere în simplitate – Aspirarea devine formalitate

Într-o situație de urgență, supraviețuirea pacientului depinde de cât de rapid și eficient i se eliberează căile respiratorii. ACCUVAC impune standardele în domeniul aspirării căilor respiratorii de mai multe decenii, asigurând eliberarea căilor respiratorii ale pacientului prin aspirarea gurii și gâtului, sau a zonei endotraheale sau bronhiale. Capacitatea ridicată de aspirare și manipularea facilă garantează un tratament rapid și eficient atât în situații de urgență, cât și în spital.

Gamă largă de aplicații, funcționare flexibilă

Domeniul de presiuni negative ale ACCUVAC Lite poate fi reglat fără limite și ajustat cu regulatorul de vid ușor de utilizat. Domeniul de reglaje permite utilizarea pompei la bebeluși, copii și adulți. Pe lângă aspirarea căilor respiratorii, ACCUVAC Lite poate fi utilizată și pentru a dezumfla atele și saltele cu vid.

O privire rapidă asupra avantajelor Dvs.

- Întrebuințări variate
- Sigură și igienică
- Ușor de manipulat, robustă
- conformă cu EN 1789, se așează în siguranță pe consola de perete din vehicul

Manipulare comodă, spectru larg de aplicații

- Capacitate ridicată de aspirare de aprox. 26 litri/minut la -0,8 bar (la admisia dispozitivului).
- Reglaj pentru vid cu un domeniu de setări infinit la -0,8 bar cu regulator de vid ușor de utilizat
- Presiunea negativă este indicată de manometru
- Aspirarea sigură a secrețiilor cu ajutorul recipientului pentru secreții autoclavabil refolosibil cu filtru de bacterii de unică folosință și protecție anti-revărsare sau sac de aspirare Serres® de unică folosință cu filtru de bacterii integrat
- Înlocuirea acumulatorului: acumulatorul poate fi înlocuit ușor din afara dispozitivului, fără scule
- Carcasă robustă fabricată din materiale rezistente la impact
- Centrul de greutate coborât împiedică răsturnarea dispozitivului

Ideală în serviile medicale zilnice

- Așezare optimă a tubului de aspirare în suportul de pe partea laterală a dispozitivului
- Desprindere de pe consola de perete cu o singură mână, prin apăsarea unui buton
- Compatibilă cu consolele de perete ACCUVAC existente
- Accesorii opționale: sac încăpător pentru accesorii, sac de protecție și/sau curea de umăr

Pentru fiecare pacient și situație de urgență

- Aspirarea secrețiilor și a resturilor de alimente
- Aspirare endotraheală și bronhială
- Poate fi utilizată la bebeluși, copii și adulți
- Dezumflă atelele și saltelele cu vid

ACCUVAC Lite
cu sistem cu recipient refolosibil, consolă de perete, sac de accesorii și cablu de alimentare de 12 V

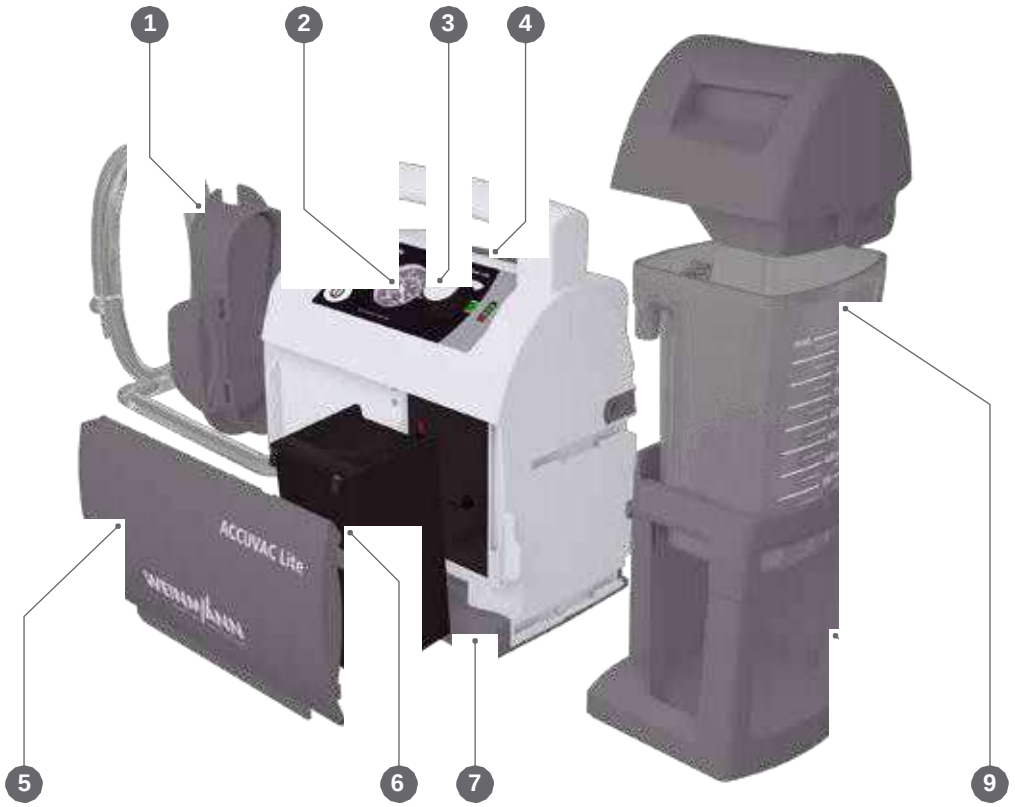
ACCUVAC Lite
cu sistem cu recipient de unică folosință, consolă de perete,
cablu de alimentare de 12 V și sac de protecție

Linia deschisă service
+49 40 88 18 96 122

Date service: ACCUVAC Lite

Garanția oferită de producător	2 ani
Interval inspecții tehnice	nu necesită inspecție
Program de întreținere	nu necesită întreținere
Verificarea stării de funcționare	manual
Înlocuirea acumulatorului	simplă, din afara dispozitivului, fără scule
Acumulator reîncărcabil	nu necesită întreținere și calibrare
Convertire sistem de unică folosință/ sistem refolosibil	simplu, fără scule

Funcționarea intuitivă oferă siguranță



1. Suport pentru tubul de aspirare
pentru depozitarea ideală

2. Manometru
indică presiunea negativă

3. Regulator de vid ușor de utilizat
domeniu de reglaje pentru vid infinit

4. Desprindere din consola de perete
eliberare cu o singură mână prin apăsarea unui buton

5. Capac compartiment acumulator
poate fi deschis fără scule pentru a accesa rapid și ușor acumulatorul

6. Acumulator reîncărcabil
acumulator pe bază de plumb cu încărcare până la 80%

7. Baza dispozitivului cu ghidaj pentru tub

8. Suport recipient
materialul rezistent la impact sporește siguranța sistemelor cu recipient

9. Recipient secreții refolosibil, 1000 ml
cu protecție anti-revărsare, filtru de bacterii de unică folosință. Dacă recipientul se umple, ACCUVAC Lite se oprește din aspirat.

Specificații tehnice

ACCUVAC Lite

Clasa produsului conform Directivei 93/42/CEE	IIa
Conf. RoHS conform Directivei 2011/65/UE (RoHS II)	Da
Clasificare conform EN ISO 10079-1	Capacitate ridicată vid/debit
Standarde utilizate	EN 60601-1, EN ISO 10079-1, EN 1789, EN 60601-1-12, EN 60601-1-11, RTCA DO-160 G
Dimensiuni (L x Î x P)	• cu sistem cu recipient 370 x 277 x 146 mm • cu sistem cu recipient + sac accesorii 370 x 277 x 152 mm
Greutate	• Dispozitivul cu acumulator, fără sistem cu recipient și suport 4,6 kg • Sistem cu recipient refolosibil cu suport 1.00 kg
Domeniu de temperaturi: Operare Transport/depozitare	între -5°C și +50°C între -40 °C și +70 °C
Consum maxim de curent	4,3 A
Tensiune nominală	12 V c.c. nominal (min. 10 V, max. 15 V)
Capacitate de aspirare la admisia dispozitivului (fără sistem cu recipient) la -0,8 bar, acumulator complet încărcat la 21°C/1013 hPa	26 litri/min
Capacitate de aspirare la admisia dispozitivului la sistemul cu recipient refolosibil la -0,8 bar, acumulator complet încărcat la 21°C/1013 hPa	23 litri/min
Reglaje de vid	Regulator de vid cu domeniu de reglaje infinit
Regim de funcționare	S2 45 min
Grad de protecție	IP34D
Tip acumulator reîncărcabil	Plumb
Acumulator reîncărcabil	• Durată încărcare Stare acumulator 80%: 2,75 ore Stare acumulator 100%: 14 ore • Ciclu de viață aprox. 400 de cicluri de încărcare • Capacitate acumulator 40 min (în regim continuu cu acumulator complet încărcat/nou)
Volum recipient secreții	1.000 ml
Tub de aspirare refolosibil	10 mm DI, 1300 mm lungime
Tub de aspirare de unică folosință	7 mm DI, 1800 mm lungime

CE 0124

Certified Quality Management System meeting EC directive 93/42/EEC, Annex II (EN ISO 9001:2008/EN ISO 13485)

Proiectat în Germania

Alegeți combinația ACCUVAC Lite preferată – concepută să vă satisfacă nevoile:

ACCUVAC Lite cu sistem cu recipient de unică folosință, WM 11705

ACCUVAC Lite cu sistem cu recipient refolosibil*, WM 11700

ACCUVAC Lite cu sistem cu recipient de unică folosință, cu sac de accesorii, WM 11745

ACCUVAC Lite cu sistem cu recipient refolosibil*, cu sac de accesorii, WM 11740

Combinați ACCUVAC Lite cu accesoriile de la pagina 6

*Rețineți că sistemul cu recipient refolosibil este dotat cu filtru de bacterii de unică folosință.

Accesorii și piese de schimb

Accesorii

1. Sac de protecție WM 11692
(nu poate fi combinat cu sacul de accesorii)

2. Curea de umăr WM 11693

3. Cablu conectare 12 V WM 10650

4. Sursă de alimentare și încărcător WM 2620
pentru curent alternativ de 100V - 240V pentru fișa ACCUVAC, inclusiv cablu de alimentare conform cu EN 50075 (Europlug)

5. Consolă de perete pentru ACCUVAC WM 15208
inclusiv set de instalare

6. Placă suport pentru balustrade standard de spital WM 15845

7. Set montaj cu două WM 15805
adaptoare pentru balustrade standard de spital

8. Consolă de perete pentru sursa de alimentare WM 15844
și încărcător

9. Consolă stâlp cu set de instalare WM 15806
diam. 19 mm - 40 mm

10. Set conversie pentru sistem cu recipient refolosibil, WM 17820
format din:
- Set, sistem cu recipient refolosibil (WM 17821)
- Suport pentru sistem cu recipient refolosibil (WM 11654)

11. Set conversie pentru sistem cu recipient refolosibil, WM 17825
format din:
- Suport pentru sistem cu recipient de unică folosință (WM 11754)
- Tub de vid pentru recipient pentru secreții Serres® (WM 11761)
- Recipient pentru secreții Serres®, complet (WM 10790)

12. Set conversie pentru sac accesorii, WM 17829
format din:
- Sac accesorii (WM 11691)
- Capac compartiment acumulator pentru sac accesorii (WM 11714)

Consumabile

13. Sac aspirare Serres® 1000 ml, cu WM 17800
filtru hidrofob și agent de solidificare
(Unitate de ambalare: 32 articole în cutie)

14. Tub de aspirare de unică folosință cu WM 10778
element de manipulare cu vârful degetului,
180 cm lungime, 7 mm DI, disponibil și
în seturi de 10, 20, 32 și 50 de tuburi

15. Tub de aspirare refolosibil 130 cm lungime, WM 10662
10 mm DI, disponibil și în seturi de
10, 20 și 50 de tuburi

16. Element de manipulare cu vârful degetului pentru tubul de aspirare refolosibil WM 10666
10 mm DI, disponibil și în seturi de
10, 20 și 50 de bucăți

17. Set de 10 filtre de bacterii de unică folosință WM 17830
pentru recipientul pentru secreții refolosibil

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Piese de schimb pentru sistemul refolosibil

1. Parte superioară capac recipient secreții WM 11657

2. Suport filtru WM 11661

3. Garnitură suport filtru WM 11663

4. Filtru bacterii de unică folosință

5. Parte inferioară capac recipient secreții WM 11658

6. Supapă cu floltor sferic WM 11662

7. Recipient secreții refolosibil 1000 ml WM 11653

8. Tub de aspirare refolosibil 10 mm DI WM 10662

9. Element de manipulare cu vârful degetului pentru tubul de aspirare refolosibil 10 mm DI WM 10666

10. Suport pentru sistem cu recipient refolosibil WM 11654

- Capac recipient secreții, complet, format din piesele de schimb 1 – 6 WM 17822
- Set, sistem cu recipient refolosibil format din piesele de schimb 1 – 9 WM 17821
- Set conversie pentru sistem cu recipient refolosibil, format din piesele de schimb 1 – 10 WM 17820

Piese de schimb pentru sistemul de unică folosință Serres®

- Recipient pentru secreții Serres®, complet, formast din:WM 10790
  - Recipient secreții, 1000 ml (WM 10775)
  - Sac aspirare
  - Tub de aspirare de unică folosință cu element de manipulare cu vârful degetului (WM 10778)
- Recipient pentru secreții Serres®, 1000 ml WM 10775
- Tub de vid pentru recipient secreții Serres® WM 11761
- Suport pentru sistem cu recipient de unică folosință WM 11754
- Set sistem cu recipient de unică folosință, format din: WM 17826
  - Tub de vid pentru recipient pentru secreții Serres® (WM 11761)
  - Recipient secreții Serres®, complet (WM 10790)
- Conector în unghi pentru recipient Serres®, refolosibil WM 10799

Piese de schimb pentru ACCUVAC Lite

- Set, clemă cu eliberare WM 17837
- Acumulator reîncărcabil cu plumb WM 10747
- Capac compartiment acumulator (fără ochi pentru sacul de accesorii) WM 11704
- Suport pentru tubul de aspirare WM 11664
- Bază dispozitiv WM 11677

Pur și simplu profesional

WEINMANN Emergency este o firmă familială, care activează pe piața internațională a tehnologiilor medicale. Soluțiile noastre de sisteme mobile pentru medicina de urgență, de transport și de dezastre, suntem cei care stabilim standarde în salvarea vieților. În strânsă colaborare cu utilizatorii profesionali din cadrul serviciilor medicale de urgență, spitale și unități medicale militare, am dezvoltat produse medical inovatoare pentru ventilare și defibrilare. De peste 100 de ani oferim clienților noștri fiabilitate de cel mai înalt nivel, o bogată experiență și calitate germană.

Sediul central
WEINMANN Emergency
Medical Technology GmbH + Co.
KG Frohbösestraße 12
22525 Hamburg
Germania

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T: +49 40 88 18 96-120 Asistență Clienți, T: +49 40 88 18 96-122 Asistență post-vânzări,
E: info@weinmann-emt.de

Centrul pentru producție, logistică, service
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Subsemnata **ŞTEFANA FORGACIU**, traducător autorizat de M. J. cu nr. **37629**,
certific exactitatea traducerii în limba română, cu textul înscrisului în copie, în limba engleză.

TRADUCĂTOR **ŞTEFANA FORGACIU** - *AUTORIZAT* cu nr. **37629**

EC - DECLARATION OF CONFORMITY
EG – KONFORMITÄTSERKLÄRUNG

We
Wir

ATMOS MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Straße 16
79853 Lenzkirch/Germany
Tel. +49 7653 689-0

declare under our sole responsibility that the medical device(s), classified as **IIa**
erklären in alleiniger Verantwortung, dass das/die Medizinprodukt(e), klassifiziert als

Suction unit, transportable
Absauggerät, Notfall

ACCUVAC Pro ACCUVAC Pro	REF WM 11601
ACCUVAC Pro with reusable canister system ACCUVAC Pro mit Mehrwegbehältersystem	REF WM 11600
ACCUVAC Pro with disposable canister system ACCUVAC Pro mit Einwegbehältersystem	REF WM 11605
ACCUVAC Pro with reusable canister system, wall mounting and 12-V connection cable ACCUVAC Pro mit Mehrwegbehältersystem, Wandhalterung u. 12 V-Verbindungsleitung	REF WM 11610
ACCUVAC Pro with disposable canister system, wall mounting and 12-V connection cable ACCUVAC Pro mit Einwegbehältersystem, Wandhalterung u. 12 V-Verbindungsleitung	REF WM 11615
ACCUVAC Pro with reusable canister system, wall mounting, accessories bag and 12-V connection cable ACCUVAC Pro mit Mehrwegbehältersystem, Wandhalterung, Zubehörtasche und 12 V-Verbindungsleitung	REF WM 11620
ACCUVAC Pro with disposable canister system, wall mounting, accessories bag and 12-V connection cable ACCUVAC Pro mit Einwegbehältersystem, Wandhalterung, Zubehörtasche und 12 V-Verbindungsleitung	REF WM 11625
ACCUVAC Pro with reusable canister system and power supply unit/ charger for 100 V - 240 V ACCUVAC Pro mit Mehrwegbehältersystem und Netz-/ Ladegerät 100 bis 240 V	REF WM 11630
ACCUVAC Pro with disposable canister system and power supply unit/ charger for 100 V - 240 V ACCUVAC Pro mit Einwegbehältersystem und Netz-/ Ladegerät 100 bis 240 V	REF WM 11635
ACCUVAC Pro with reusable canister system and accessories bag ACCUVAC Pro mit Mehrwegbehältersystem und Zubehörtasche	REF WM 11640
ACCUVAC Pro with disposable canister system and accessories bag ACCUVAC Pro mit Einwegbehältersystem und Zubehörtasche	REF WM 11645

ACCUVAC Lite ACCUVAC Lite	REF WM 11701
ACCUVAC Lite with reusable canister system ACCUVAC Lite mit Mehrwegbehältersystem	REF WM 11700
ACCUVAC Lite with disposable canister system ACCUVAC Lite mit Einwegbehältersystem	REF WM 11705
ACCUVAC Lite with reusable canister system, wall mounting and 12-V connection cable ACCUVAC Lite mit Mehrwegbehältersystem, Wandhalterung u. 12 V-Verbindungsleitung	REF WM 11710
ACCUVAC Lite with disposable canister system, wall mounting and 12-V connection cable ACCUVAC Lite mit Einwegbehältersystem, Wandhalterung u. 12 V-Verbindungsleitung	REF WM 11715
ACCUVAC Lite with reusable canister system, wall mounting, accessories bag and 12-V connection cable ACCUVAC Lite mit Mehrwegbehältersystem, Wandhalterung, Zubehörtasche und 12 V-Verbindungsleitung	REF WM 11720
ACCUVAC Lite with disposable canister system, wall mounting, accessories bag and 12-V connection cable ACCUVAC Lite mit Einwegbehältersystem, Wandhalterung, Zubehörtasche und 12 V-Verbindungsleitung	REF WM 11725
ACCUVAC Lite with reusable canister system and power supply unit/ charger for 100 V - 240 V ACCUVAC Lite mit Mehrwegbehältersystem und Netz-/ Ladegerät 100 bis 240 V	REF WM 11730
ACCUVAC Lite with disposable canister system and power supply unit/ charger for 100 V - 240 V ACCUVAC Lite mit Einwegbehältersystem und Netz-/ Ladegerät 100 bis 240 V	REF WM 11735
ACCUVAC Lite with reusable canister system and accessories bag ACCUVAC Lite mit Mehrwegbehältersystem und Zubehörtasche	REF WM 11740
ACCUVAC Lite with disposable canister system and accessories bag ACCUVAC Lite mit Einwegbehältersystem und Zubehörtasche	REF WM 11745

meet(s) all applicable requirements of the Directive 93/42/EEC.
allen anwendbaren Anforderungen der Richtlinie 93/42/EWG entspricht/ entsprechen.

Name, address and identification number of Notified Body:
Name, Adresse und Kennnummer der Benannten Stelle:

DEKRA Certification GmbH, Handwerkstraße 15, D-70565 Stuttgart **0124**

Conformity assessment procedure:	Directive 93/42/EEC Annex II on medical products, passed by the commission on 14th June 1993, last amended on 5th September 2007
Konformitätsbewertungsverfahren:	Richtlinie 93/42/EWG Anhang II des Rates über Medizinprodukte vom 14. Juni 1993, zuletzt geändert am 5. September 2007

Valid till further changes on the product until May 26st 2024.
Gültig bis auf weitere Änderungen am Produkt bis 26. Mai 2024.

Lenzkirch, 01.04.2020
Place and date of issue

i.V. Andreas Heer
Head of Quality Management

i.V. Steffi Focke
Quality Management

VT-0179-16

SINGLE PATIENT HAND SUCTION UNIT

Code:	**28131**
Category:	**Manual aspirators**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I S**
NSIS:	**2426726**
CND:	**Z120105**
EAN13:	**8023279281316**

Description:

SINGLE PATIENT HAND SUCTION PUMP

Light and portable manual suction unit operated by one hand only to let the other hand free for important duties.
Simple operation.
Adjustable stroke knob provides different suction pressures.

Supplied with 550 mmHg handle, 300 ml canister, child and adult catheter

Technical Specifications:

Vacuum after 1 min at 20kPa vacuum: = 15 kPa
Vacuum after 6 times suction: = 20 kPa
Max. vacuum: = 39.9 kPa
Disposable container volume: 300 ml
External cap: Ø 17 mm
External catheter connection: Ø 17 and 9 mm
Stroke adjustment: turn to 50% or 100%
Size - weight: 52x42x44 cm - 230 g

EC Certificate

TÜVRheinland

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60132442 0001

Report No.: 15060022 007

Manufacturer:
Jiangsu Maslech Medical
Technology Co., Ltd.
Building G39, The Third Period
Factory Area, China Medical City
Taizhou City
225300 Jiangsu
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60109154 0001

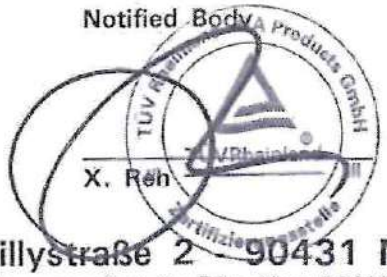
Expiry Date: 2023-06-08

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-09-18

Date: 2018-09-18

Notified Body



X. Reh

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: HD 60132442 0001
Report No.: 15060022 007

Manufacturer: Jiangsu Maslech Medical
Technology Co., Ltd.
Building G39, The Third Period
Factory Area, China Medical City
Taizhou City
225300 Jiangsu
China

Products:

Implantable Ligating Clips, Disposable Biopsy Forceps, Disposable Retrieval Devices, Disposable Sheath Trocars, Disposable Cervical Brushes, Disposable Suction Irrigation Devices

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Laryngoscopes, Manual Suction Units

Notified Body

Date: 2018-09-18

X. Ren

corpuls®

FOCUS – ON – PATIENTS

corpuls^3

I AM NO HERO
IT'S MY JOB

THE "3" IN CORPULS3

THE LIFE-SAVING MULTITALENT

The **corpuls3** is not only a device.
It is a three module system:

- **Monitoring Unit**
- **Patient Box**
- **Defibrillator/Pacer**

The modules can be separated at any time, as and when required. They communicate wirelessly, eliminating annoying cables. The **corpuls3** adapts optimally to the users needs. Legendary and still unique, the **corpuls3** is used successfully by hundreds of organizations around the world.

THE MONITORING UNIT

The Monitoring Unit is basically the command bridge and control centre of the **corpuls3**. At just 2.7 kg, including the battery and printer paper, it is about as thick as a newspaper and can be comfortably held in one hand.

FULL CONTROL

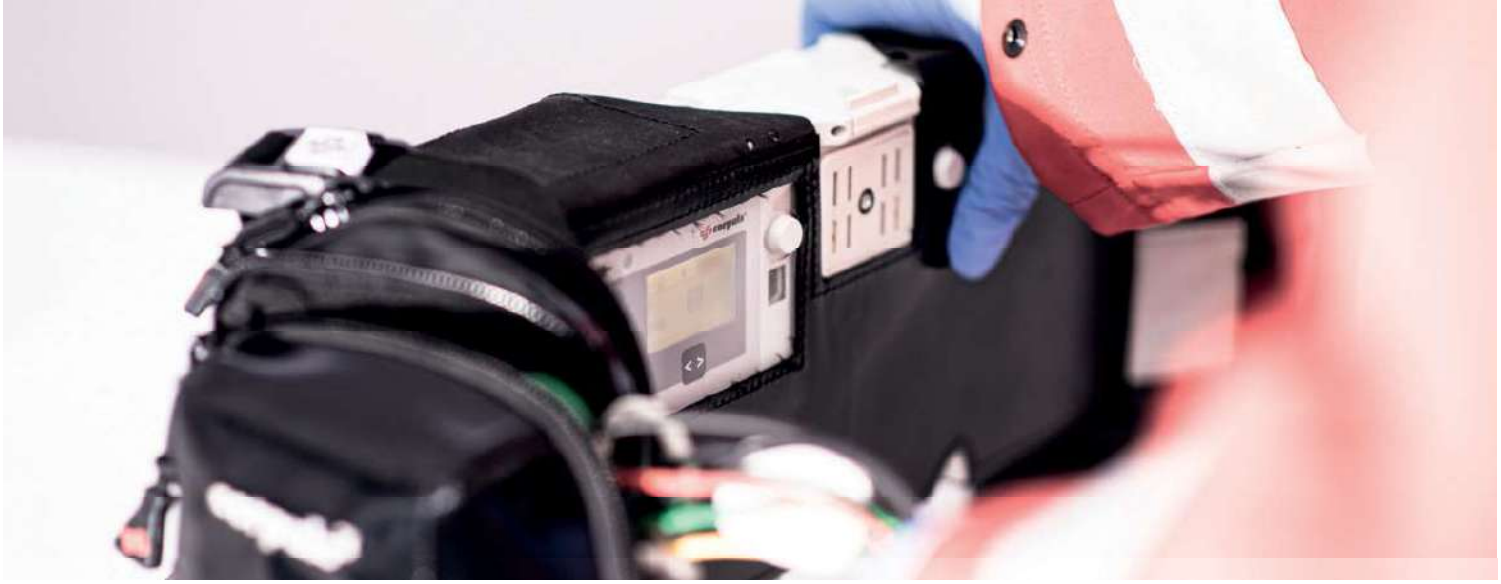
Up to 6 curves and 13 vital parameters can be displayed simultaneously on the brilliant 8.4" display. Fully customisable, freely namable and – in case of the NIBP display – with quality indicator. So paramedics and emergency physicians always have exactly the information they need at a glance. No more and no less.
In addition, up to 6 curves can be printed in real time using the wide printer.

FULL COMMUNICATION

The built-in connectivity features like Wi-Fi and GSM are ideal for telemedicine and the **corpuls** telemetry solution **corpuls.web**.

SPECIFICATIONS

- Large, transflective colour display (8.4")
- Up to 6 curves and 13 vital parameters can be displayed
- Diagnostic 12-lead ECG preview
- Views can be freely configured and named
- GSM Modem, Wi-Fi or LAN Port for data transmission/live streaming
- Wide printer (106 mm) with simultaneous real-time printout of up to 6 curves
- 7 softkeys and function keys for quick access to important menu items
- Intuitive operating concept with jog dial for easy menu control
- 1-2-3 operation in defibrillation modes
- All-around impact protection
- Weighs only 2.7 kg
- Integrated insurance card reader



THE PATIENT BOX

The Patient Box is the "heart" of the system.
Here, all vital parameters and measured values are collected, measured and stored. Be it a 12-lead ECG, SpO_2 or NIBP – the Patient Box sends the recorded values from the pre-connected sensors to the Monitoring Unit and stores them.

This also means that all the sensor cables can remain with the patient. Thus keeping them out of the way and enabling seamless monitoring during patient transport e.g. through a narrow staircase.

SEPARATE DISPLAY

Thanks to its own display, important vital parameters such as heart rate or NIBP can also be monitored directly on the Patient Box. If required, these parameters as well as audio and acoustic alarms can be recorded by the Patient Box.

CONSTANT COMPANION

Weighing between 1 and 1.3 kg, depending on the features, the Patient Box is so compact that it can remain with the patient.

SPECIFICATIONS

- 12-lead diagnostic ECG, heart rate
- HES ECG analysis software
- Masimo Rainbow SET® Technology to measure SpO_2, PR, PI, SpCO, SpMet, SpHb
- (Automated) non-invasive blood pressure measurement (SunTech®)
- CO_2 measurement with main stream capONE® technology (also for non-intubated patients) (Nihon Kohden)
- **corPatch CPR**-Feedback (ZOLL M. C.)
- 2 channels for temperature measurement
- 4 channels for invasive pressure measurement (e.g., arterial/venous and intra-cranial pressure)
- Separate display for vital parameters, remaining time and alarms
- Acoustic alarm indicator
- Microphone for audio recording
- Data export via CompactFlash®
- Weighs 1.3 kg max
- PAX® accessory bag for cables and sensors
- Bluetooth

THE DEFIBRILLATOR

The modular design of the **corpuls3** allows complete mechanical separation of the Defibrillator/Pacer. The modules remain wirelessly connected. As a result, the weight of the **corpuls3** system can be almost halved – ideal for better mobility and flexibility in a time-critical transfer of the patient e.g. from ambulance to clinic. This also allows shock delivery from a safe distance via the Monitoring Unit (using **corPatch** therapy electrodes).

▶ Alternative Defibrillator-/ Pacer Unit

▶ Defibrillator-/Pacer Unit SLIM

SPECIFICATIONS

- Biphasic rectangular impulse, impedance compensated
- 2 to 200 Joules, configurable energy protocol
- AED and manual defibrillator
- AED protocol according to the current Guidelines, up-datable at any time
- Pre-connected **corPatch** therapy electrodes in separate bag
- Use with shock paddles as well as internal shock spoons is possible
- Pacer with FIX-, DEMAND- and OVERDRIVE mode
- Weighs only 2.3 kg (**corpuls3** SLIM)
- Up to 200 shocks with fully charged battery

ENERGY MANAGEMENT

The best energy management is one the user doesn't have to think about. The intelligent energy management of the **corpuls3** fulfills exactly this requirement. The **corpuls3** is always ready for use when removed from the vehicles charging bracket. When the device is placed back in the charging bracket, the batteries are charged automatically and the **corpuls3** is ready for the next use. Time-consuming and error-prone manual charging and replacing of batteries is therefore eliminated and the user can concentrate completely on the patient. The batteries for the three modules are identical and extremely powerful.

In compact mode simply use the battery reserves of the other modules. As a result, there is always enough power available for long-term use to ensure comprehensive monitoring and therapy with the Defibrillator/Pacer.

▶ Magnetic charging contact "MagCode"

BRACKETS

There is a solution for every requirement:
Brackets for the wall and floor, with or without swivel mechanism, or secure attachments for stretchers from different manufacturers.

Most brackets are compliant with EN 1789 and tested with an acceleration of up to 24 g instead of the defined 10 g. Furthermore, brackets are optionally available with or without integrated power supply.

PATIENT BOX

- Adapter solutions for common stretcher systems
- Easy mounting and release
- 12 VDC, 100 VAC - 240 VAC (50 Hz - 60 Hz)

MONITOR

- Slim installation depth, light weight
- Also fits Monitor and Patient Box combination
- 12 VDC, 100 VAC - 240 VAC (50 Hz - 60 Hz)

COMPACT DEVICE

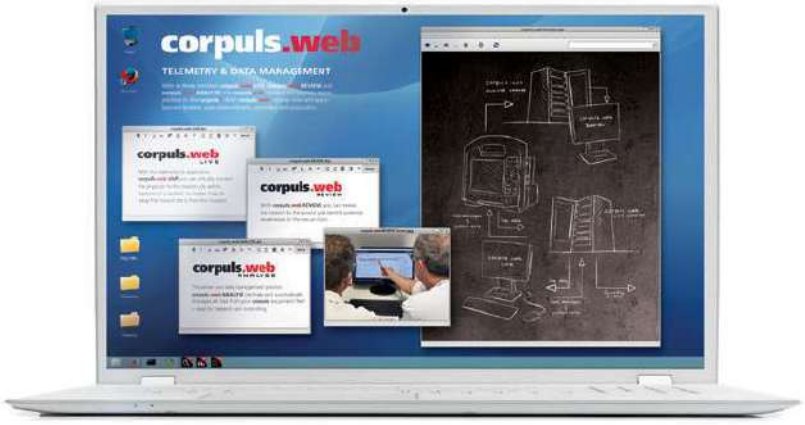
- One-hand release via the handle
- Self-locking mechanism activated after 10 seconds
- 12 VDC, 100 VAC - 240 VAC (50 Hz - 60 Hz)

THE SMART THINKING ACCESSORY

corpuls control is a revolutionary add-on product for the **corpuls3**. It is also our first step into the world of mobile applications.

The idea behind it: It is not always possible for rescuers to work on a patient without endangering themselves. For example, during a mission in an ambulance or during a turbulent rescue flight, there is always the danger that rescue personnel could lose their balance. A fall can have dire consequences for both the rescue personnel and the patient. It is safer for the crew when they are strapped into their seats. But then the patient monitor may not be in reach. The solution to this problem: **corpuls control**

TELEMETRY & DATA MANAGEMENT



With its three members: **corpuls.web LIVE**, **corpuls.web REVIEW** and **corpuls.web ANALYSE**, the **corpuls.web** family is the optimal, digital addition to the **corpuls3**. **corpuls.web** offers you limitless time and space, more efficiency and control during a mission.

corpuls.web LIVE

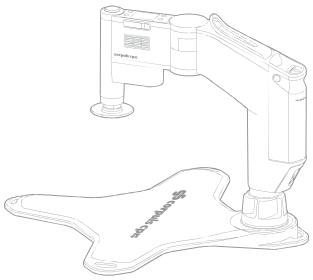
With the telemedicine application **corpuls.web LIVE** you can virtually connect the physician to the mission site within a fraction of a second, no matter how far away the site is from the clinic.

corpuls.web ANALYSE

The server and data management solution **corpuls.web ANALYSE** centrally and automatically manages all data from your **corpuls** equipment fleet – ideal for quality management and controlling.

corpuls.web REVIEW

With **corpuls.web REVIEW**, you can review the mission down to the second. Exactly what is required for optimal debriefing and the best possible documentation for quality assurance.



For over 35 years, **corpuls**® has developed and produced innovative high-end equipment for emergency and intensive care medicine. Today, in our headquarters in Kaufering, over 250 hearts each beat around 50,000 times every work day while aspiring to meet the high standards of rescue workers from over 60 countries around the world.

corpuls defibrillators, patient monitoring systems and chest compression devices have set the standard since day one in realising the most advanced insights in medical science, innovation and ergonomics – thus guaranteeing reliable and trusted help in the fight for human lives.

corpuls®

Manufacturer:
corpuls | GS Elektromedizinische Geräte
G. Stemple GmbH
Hauswiesenstrasse 26 | 86916 Kaufering | Germany

Telephone +49 8191 65 722-0
E-mail info@corpuls.com
Web www.corpuls.world

CE 0123

Bayerns Best 50 Preisträger 2018

Deutschland Land der Ideen
Ausgewählter Ort 2012

Medical Technology Made in Germany

Art.-Nr. 76139.32020 Vers. 1.0 (12/19)

Declaration of Conformity

GS Elektromedizinische Geräte G. Stemple GmbH

Hauswiesenstraße 26
86916 Kaufering

Germany

Product name	Defibrillators with monitor
Technichal Documentation Reference Number	10_003
DoC Version Number	#04

declares under its sole responsibility, that the product including the accessories listed in Appendix I, to which the declaration relates, fulfills the essential requirements according to Annex I of the **Directive 93/42/EEC** on Medical Devices. According to the risk class of the product the following conformity assessment has been carried out via the following conformity assessment routes:

Conformity Assessment Routes:

Risk Class I:	Annex VII
Risk Class Is:	Annex VII combined with Annex V *)
Risk Class Im:	Annex VII combined with Annex V *)
Risk Class IIa:	Annex II without (4) *)
Risk Class IIb:	Annex II without (4) *)
Risk Class III:	Annex II including (4) *)

***) Notified Body**	TÜV Süd Product Service GmbH Ridlerstraße 65, 80339 München, Germany
***) EC Certificate number(s)**	G1 019931 0008 Rev. 01

Unless this Declaration of conformity is replaced by another Declaration of Conformity, this declaration is **valid until**

2024-05-26

GS Elektromedizinische Geräte
G. Stemple GmbH

Kaufering (Germany), 2022-06-03

Christian Podolak
Vice President Quality Management & Regulatory Affairs

GS Elektromed. Geräte G. Stemple GmbH
Hauswiesenstr. 26
D-86916 Kaufering

Managing Board: K. Stemple, Dr. C. Klimmer, I. Klimmer
Registergericht · Court of Registry Augsburg HRB 3373
USt-Id. · VATnumber DE 128 668 535

Volksbank Kaufering, bank account:
IBAN DE20 7009 3200 0008 6801 24
BIC GENODEF1STH

Appendix I
Declaration of Conformity

Article no.	Description	Software Version (up to)	Risk class	GMDN Code	UMDNS Code	Remark
04000	Base model corpuls³ consisting of: • 04100 • 04200 • 04300	4.x	IIb	17882	17-882	See subsequent positions
04100	Display Unit corpuls³	4.x	IIb	17882	17-882	
04200	Patient Box corpuls³	4.x	IIb	17882	17-882	
04300	Defib Unit corpuls³	4.x	IIb	17882	17-882	
04000.1	NVG/ NVIS compatible consisting of: • 04100.1 • 04200.1 • 04300.1	4.x	IIb	17882	17-882	See subsequent positions
04100.1	Display Unit corpuls³	4.x	IIb	17882	17-882	
04200.1	Patient Box corpuls³	4.x	IIb	17882	17-882	
04300.1	Defib Unit corpuls³	4.x	IIb	17882	17-882	
04000.2	HBO approved consisting of: • 04100.2 • 04200.2 • 04300.2	4.x	IIb	17882	17-882	See subsequent positions
04100.2	Display Unit corpuls³	4.x	IIb	17882	17-882	
04200.2	Patient Box corpuls³	4.x	IIb	17882	17-882	
04300.2	Defib Unit corpuls³	4.x	IIb	17882	17-882	
04001	Base model corpuls³ slim consisting of: • 04100 • 04200 • 04301	4.x	IIb	17882	17-882	See subsequent positions
04100	Display Unit corpuls³	4.x	IIb	17882	17-882	
04200	Patient Box corpuls³	4.x	IIb	17882	17-882	
04301	Defib corpuls³ SLIM	4.x	IIb	17882	17-882	

GS Elektromed. Geräte G. Stemple GmbH
Hauswiesenstr. 26
D-86916 Kaufering

Managing Board: K. Stemple, Dr. C. Klimmer, I. Klimmer
Registergericht · Court of Registry Augsburg HRB 3373
USt-Id. · VATnumber DE 128 668 535

Volksbank Kaufering, bank account:
IBAN DE20 7009 3200 0008 6801 24
BIC GENODEF1STH

Article no.	Description	Software Version (up to)	Risk class	GMDN Code	UMDNS Code	Remark
04001.1	Base model corpuls3 slim NVG/NVIS consisting of: • 04100.1 • 04200.1 • 04301	4.x	IIb	17882	17-882	See subsequent positions
04100.1	Display Unit corpuls3	4.x	IIb	17882	17-882	
04200.1	Patient Box corpuls³	4.x	IIb	17882	17-882	
04301	Defib corpuls³ SLIM	4.x	IIb	17882	17-882	
04002	Base model corpuls³ Touch consisting of: • 04101 • 04201 • 04302	4.x	IIb	17882	17-882	See subsequent positions
04101	Display Unit corpuls³ Touch	4.x	IIb	17882	17-882	
04201	Patient Box corpuls³ Touch	4.x	IIb	17882	17-882	
04302	Defib corpuls³ Touch SLIM	4.x	IIb	17882	17-882	
04002.1	Base model corpuls3 Touch NVG/NVIS consisting of: • 04101.1 • 04201.1 • 04302	4.x	IIb	17882	17-882	See subsequent positions
04101.1	Display Unit corpuls³ Touch NVG/NVIS	4.x	IIb	17882	17-882	
04201.1	Patient Box corpuls³ Touch NVG/NVIS	4.x	IIb	17882	17-882	
04302	Defib corpuls³ Touch SLIM	4.x	IIb	17882	17-882	
04003	Base model corpuls³ MAX consisting of: • 04100 • 04200 • 04303	4.x	IIb	17882	17-882	See subsequent positions
04100	Display Unit corpuls³	4.x	IIb	17882	17-882	
04200	Patient Box corpuls³	4.x	IIb	17882	17-882	
04303	Defib corpuls³ MAX	4.x	IIb	17882	17-882	

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Volksbank Kaufering, bank account:
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Article no.	Description	Software Version (up to)	Risk class	GMDN Code	UMDNS Code	Remark
04003.1	NVG/ NVIS compatible consisting of: • 04100.1 • 04200.1 • 04303.1	4.x	IIb	17882	17-882	See subsequent positions
04100.1	Display Unit corpuls³	4.x	IIb	17882	17-882	
04200.1	Patient Box corpuls³	4.x	IIb	17882	17-882	
04303.1	Defib corpuls³ MAX	4.x	IIb	17882	17-882	
04004	Base model corpuls³ slim MAX consisting of: • 04100 • 04200 • 04304	4.x	IIb	17882	17-882	See subsequent positions
04100	Display Unit corpuls³	4.x	IIb	17882	17-882	
04200	Patient Box corpuls³	4.x	IIb	17882	17-882	
04304	Defib corpuls³ SLIM MAX	4.x	IIb	17882	17-882	
04004.1	Base model corpuls3 slim MAX NVG/NVIS consisting of: • 04100.1 • 04200.1 • 04304	4.x	IIb	17882	17-882	See subsequent positions
04100.1	Display Unit corpuls³	4.x	IIb	17882	17-882	
04200.1	Patient Box corpuls³	4.x	IIb	17882	17-882	
04304	Defib corpuls³ SLIM MAX	4.x	IIb	17882	17-882	
04005	Base model corpuls³ Touch MAX consisting of: • 04101 • 04201 • 04305	4.x	IIb	17882	17-882	See subsequent positions
04101	Display Unit corpuls3 Touch	4.x	IIb	17882	17-882	
04201	Patient Box corpuls3 Touch	4.x	IIb	17882	17-882	
04305	Defib corpuls³ Touch SLIM MAX	4.x	IIb	17882	17-882	

GS Elektromed. Geräte G. Stemple GmbH
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USt-Id. · VATnumber DE 128 668 535

Volksbank Kaufering, bank account:
IBAN DE20 7009 3200 0008 6801 24
BIC GENODEF1STH

Article no.	Description	Software Version (up to)	Risk class	GMDN Code	UMDNS Code	Remark
04005.1	Base model corpuls3 Touch MAX NVG/NVIS consisting of: • 04101.1 • 04201.1 • 04305	4.x	IIb	17882	17-882	See subsequent positions
04101.1	Display Unit corpuls³ Touch NVG/NVIS	4.x	IIb	17882	17-882	
04201.1	Patient Box corpuls³ Touch NVG/NVIS	4.x	IIb	17882	17-882	
04305	Defib corpuls³ Touch SLIM MAX	4.x	IIb	17882	17-882	

GS Elektromed. Geräte G. Stemple GmbH
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USt-Id. · VATnumber DE 128 668 535

Volksbank Kaufering, bank account:
IBAN DE20 7009 3200 0008 6801 24
BIC GENODEF1STH

EU Declaration of Conformity

GS Elektromedizinische Geräte G. Stemple GmbH
Hauswiesenstraße 26
86916 Kaufering
Germany

declares under its sole responsibility that the products in the attached Appendix I:

Product name	Charging Brackets
Technical Documentation Reference Number	99_690
DoC Version Number	00

[x] comply with the provisions of **Directive 2011/65/EU** on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

[ ] comply with the essential requirements and relevant provisions of **Directive 2014/53/EU** on radio equipment.

Conformity assessment procedure:

- [ ] Internal Production Control (Annex II)
- [ ] EU-type examination (Annex III)
- [ ] Conformity to type based on internal production control (Annex III)
- [ ] Conformity based on full quality assurance (Annex IV)
- [ ] Notified body involved:
  Name:
  No.:
  Certificate no.:

Accessories / Software necessary for the radio equipment to be used as intended and covered by this declaration:

- [ ] See Appendix III
- [x] none

[ ] meet the requirements of **Regulation No 10** of the Economic Commission for Europe of the United Nations (**UN/ECE**): 'Uniform provisions concerning the approval of vehicles with regard to electromagnetic compatibility'.

[x] comply with the provisions of **Regulation (EU) 2017/745** on medical devices.

SRN (Single Registration Number): N/A

According to the risk class of the product the following conformity assessment has been carried out via the following conformity assessment routes:

Conformity assessment routes:

Risk Class I:	Annex II combined with Annex III
Risk Class Is:	Annex IX (chapter I + III) combined with Annex II and III
Risk Class Im:	Annex IX (chapter I + III) combined with Annex II and III
Risk Class Ir:	Annex IX (chapter I + III) combined with Annex II and III
Risk Class IIa:	Annex IX (chapter I + III and section 4 of chapter II) combined with Annex II and III
Risk Class IIb:	Annex IX (chapter I + III and section 4 of chapter II) combined with Annex II and III
Risk Class III:	Annex IX combined with Annex II and III

[ ] **Notified body involved:**

Name: TÜV Süd Product Service GmbH
Ridlerstraße 65, 80339 München, Germany

No.: 0123

Certificate no.: N/A

Unless this Declaration of conformity is replaced by another Declaration of Conformity, this declaration is **valid until**

2025-11-18

Kaufering, 2021-07-16

Christian Podolak
Vice President Quality Management & Regulatory Affairs

Signed for and on behalf of
GS Elektromedizinische Geräte G. Stemple GmbH

[x] applies
[ ] does not apply

Appendix I
Declaration of Conformity

Article-No.	Product name	Software Version (up to)	from serial number (only for RED)	GMDN Code (only for MDR)	UMDNS Code (only for MDR)	CND (Italian Nomenclature code) - only for MDR)	Basic-UDI-DI (only for MDR)	Risk class (only for MDR)	Class. Rule (only for MDR)	TD#	Remark
04400.CA	Ladehalt. Defi-/Schrittm.-einh. 12V DC,o. Kabel/ *Charging bracket Defib mod. 12V DC, w/o cable*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A
04401.002CA	Ladehalt. Monitor, Kabel 1.5m, Cannon/ *Charging bracket Monitor, cable 1.5m,Cannon*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A
04401.003CA	Ladehalt. Monitor, Kabel 1.5m, MagCodePro/ *Charging bracket Monitor, cable 1.5m, MagCodePro*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A
04401.041CA	Ladehalt.Monitor, Kabel 2.0m, Molex /*Charging bracket Monitor, cable 2.0m, Molex*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A
04401.CA	Ladehalt. Monitor 12V DC, Kabel 1.5m, Bordnetz/ *Charging bracket Monitor, 12V DC, cable 1.5m*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A
04402	Ladehalt. Pat.-box 12V DC, Kabel 1.5m, Bordnetz/ *Charging bracket P-box, 12V DC, cable 1.5m*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A

04402.003	Ladehalt. Pat.-box 12V DC, Kabel 1.5m, MagCodePro/ *Charging bracket P-box, 12V DC, 1.5m, MagCodePro*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A
04402.041	Ladehalt. Pat.-box, Kabel 2.0m, Molex/ *Charging bracket P-box, cable 2.0m, Molex*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A
04402.06	Ladehalt. Pat.-box 12V DC, Kabel 0.1m, Bordnetz/ *Charging bracket P-box, 12V DC, cable 0.1m*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A
04402.07	Ladehalt. Pat.-box 12V DC, Kabel 3.0m, Bordnetz/ *Charging bracket P-box, 12V DC, cable 3.0m*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A
05400.1	Ladehalt. c1 12V DC, ohne Kabel/ *Charging bracket c1, 12V DC, w/o cable*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A
05405.1	Ladehalt. c1 12V DC für Ladehalt. c3 / *Charging bracket c1, 12V DC f. charging bracket c3*	N/A	N/A	61434	11-835	Z12030580	42601783500011HW	I	1	99_690	N/A

Appendix II to the EU Declaration of Conformity

Harmonised standards / other technical specifications with which the product is in conformity and on the basis of which conformity with the provisions of the following directive(s) is declared

Directive 2011/65/EU (RoHS):

n.a.

Directive 2014/53/EU (Radio equipment)

HEALTH & SAFETY (Art. 3(1)(a)):

n.a.

EMC (Art. 3(1)(b)):

n.a.

SPECTRUM (Art. 3(2)):

n.a.

Regulation (EU) 2017/745 (Medical devices):

IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012
IEC 60601-1-6:2010, AMD1:2013
IEC 60601-1-2:2014
IEC 62366:2007 + A1:2014
ISO 10993-1:2018
EN 1041:2008 + A1:2013
ISO 15223-1:2016
ISO 14971:2019
IEC 60601-1-2:2014
IEC 60601-1-12:2014
EN 1789:2014 + A1:2020
EN 13718-1:2014
EN 60529:1991 + A1:2000

Appendix III to the EU Declaration of Conformity (Radio equipment)

Accessories, Parts, Software which enable(s) the radio equipment to be used as intended and is/are covered by this declaration

Article-No.	Description
N/A	N/A

Software-Version: N/A

FLEXI DIGITAL THERMOMETER °C - std. Box flexible tip, water-proof

Code: 25563

Category: Digital thermometers

Unit of sale: 1 pc.

Minimum order: 1

Type: Medical device

Class: II A

NSIS: 18156

CND: V03010102

EAN13: 8023279255638

Description:

FLEXI DIGITAL THERMOMETER °C - hang boxfl exible tip, water-proof

Provide accurate and quick read-out. Safe and easy to use with clear and large display.

- display range 32.0°C- 42.9°C
- accuracy ±0.1°C
- memory: last reading
- beeper function and auto shut-off
- plastic case
- multilanguage manual and box (GB, FR, IT, ES, PT, GR)

Works with battery LR/4I - 1.5V

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

GIMA S.p.A.

Sede Operativa / *Operational Headquarter:*
Via Marconi, 1
20060 Gessate, MI - Italia

Sede Legale / *Registered Headquarter*
Via Tommaso Grossi, 2
20121 Milano, MI - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*
Dispositivi per aerosolterapia / *Aerosol therapy devices*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*
Dispositivi per la misurazione della saturazione di ossigeno / *Oxigen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Rif. rapporto di audit/ *Ref. audit report:* del/dated 1-2/3/2021

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:11:29

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1104

Marca / *Brandname:*
VEGA / SUPER VEGA / TOBI / SUPER TOBI / TOBI CLINIC / TOBI HOSPITAL / CLINIC PLUS / HOSPI PLUS

Modello / Model:

Aspiratori chirurgici / Surgical aspirators

Codici / Codes:

28220 ; 28216 ; 28209 ; 28214 ; 28210 ; 28232 ; 28211 ; 28202 ; 28212 ; 28233 ; 28243 ; 28234 ; 28222 ; 28194 ; 28224; 28196 ; 28208 ; 28198 ; 28190 ; 28200 ; 28191 ; 28192 ; 28201 ; 28231 28203 ; 28215 ; 28204 ; 28193 ; 28183 ; 28182

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Kit ORL sterile / Sterile ENT kit

Codici / Codes:

31456

Modello / Model:

Kit pap test / Pap smear kit

Codici / Codes:

29704

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Chief Operating Officer
Giampiero Belcredi

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Data:25/05/2021 10:11:56

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
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Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Modello / Model:

Spatula cervicale monouso sterile in plastica o legno / Disposable sterile plastic or wooden cervical spatula
Codici / Codes:

29745 ; 29748-29749

Modello / Model:

Speculum vaginale monouso sterile perno centrale - mix / Disposable sterile vaginal speculum central pin – mix
Codici / Codes:

29991

Modello / Model:

Speculum vaginale monouso sterile perno centrale - piccolo, medio, grande / Disposable sterile vaginal speculum central pin - small, medium, large
Codici / Codes:

29946 ; 29947 ; 29948

Modello / Model:

Speculum vaginale monouso sterile tache - mix / Disposable sterile vaginal speculum tache - mix
Codici / Codes:

29987

Modello / Model:

Speculum vaginale monouso sterile vite centrale - mix / Disposable sterile vaginal speculum middle screw - mix
Codici / Codes:

29995

Modello / Model:

Speculum vaginale monouso sterile vite laterale - mix / Disposable sterile vaginal speculum side screw - mix
Codici / Codes:

29986

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:12:15

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Modello / Model:

Speculum vaginale monouso sterile vite laterale (piccolo, medio, grande) / Disposable sterile vaginal speculum side screw - small, medium, large
Codici / Codes:

29983; 29984 ; 29985 ; 29976; 29977, 29978

Modello / Model:

Tampone di trasport in plastica sterile / Sterile plastic transport swab
Codici / Codes:

29753

Marca / *Brandname:*
Gimabrush Ball / Gimabrush / Gima Collector
Modello / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes
Codici / Codes:

29735 ;29736 ; 29737

Classe di rischio / *Risk class:*
II a
Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)
Modello / Model:

Proctoscopio adulti / Adult proctoscope
Codici / Codes:

25957

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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di Kiwa Italia Holding S.r.l.
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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:12:32

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
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Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per aerosolterapia / *Aerosol therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1102

Modello / Model:

Aerosol a pistone adulti e bambini / Adult and Kids compressor nebulizers

Codici / Codes:

28091 ; 28092

Marca / *Brandname:*
EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Codici / Codes:

28097; 28105

Marca / *Brandname:*
MISTRAL

Modello / Model:

Aerosol professionale a pistone per uso domiciliare / Professional compressor nebulizers for home healthcare environment

Codici / Codes:

28102

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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:12:51

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements
Codice NANDO / *NANDO codes:*
MD 0104

Marca / *Brandname:*
BOSTON / DALLAS / GIMATONO / LONDON / ROMA / TOKIO / TECNICO PROFEXIONAL / DAYTON
Modello / Model:
Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers
Codici / Codes:
32731 ; 32747; 32749 ; 32719 ; 32725; 32726 ; 32709; 32727; 32728; 32738; 32734 ; 32693/10965 ; 32735 ; 32745

Marca / *Brandname:*
SIRIO
Modello / Model:
Manometro Aneroide / Aneroid manometer
Codici / Codes:
32904

Marca / *Brandname:*
YTON
Modello / Model:
Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers
Codici / Codes:
32720; 32703; 32693; 32701

Classe di rischio / *Risk class:*
II a
Codice NANDO / *NANDO codes:*
MD 1302, MDS 7010

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:13:13

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*

Modello / Model:

Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital SphygmomanometersWRIST / ARM

Codici / Codes:

32926 ; 32924; 32924 SC

Modello / Model:

Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

Codici / Codes:

32800; 32801

Marca / *Brandname:*
DOMINO

Modello / Model:

Sfigmomanometri Digitali / Digital Sphygmomanometers

Codici / Codes:

32803; 32804

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della saturazione di ossigeno / *Oxigen saturation measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MD 0104, MDS 7010

Modello / Model:

Pulsoximetri / Pulse oximeters

Codici / Codes:

34266; 34282; 34285, 34285-10997, 34340; 34342; 34265; 35091; 35092; 35093; 35095; 35090 ; 35100

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Data:25/05/2021 10:13:36

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MD 0104, MDS 7010

Marca / *Brandname:*
DIGIT / DIGIT KIDS FARMAMED

Modello / Model:

NUB -Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

10980

Marca / *Brandname:*
FARMAMED / LINEA F / CARREFOUR / GS /PBpharma / 36.2 T&B / SUCCHIOTTO °C / BASALE / GIMA

Modello / Model:

Termometri clinici digitali classici e flessibili / Digital clinical thermometers classic and flexible

Codici / Codes:

25560; 305026-10945; 25561; 25560-10907; 305027-10946 ; 25608

Marca / *Brandname:*
FARMAMED / LINEA F / GIMA

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

25563 ; 25562

Marca / *Brandname:*
PBpharma /GIMA

Modello / Model:

Termometri clinici digitali auricolari e frontali multifunzione / Digital clinical ear and ahaed multifunction thermometers

Codici / Codes:

25580 ; 25585

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Data:25/05/2021 10:13:57

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements
Codice NANDO / *NANDO codes:*
MD 1301, MD 0104

Modello / Model:

Altimetro - Plicometro - Metro per neonati / Height meter - Skinfold caliper - Baby measuring meter
Codici / Codes:

27335 ; 27344; 27331

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Classe di rischio / *Risk class:*
II a
Codice NANDO / *NANDO codes:*
MD 0101, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Cannule di Guedel sterili / Sterile Guedel airways
Codici / Codes:

34431, 34432, 34433, 34434, 34435, 34436, 34437, 34438; 34383; 34439

Modello / Model:

Maschere in silicone autoclavabili / Maschere autoclavabili in silicone GIMA PLUS / Silicone autoclavable face masks / Silicone autoclavable face masks GIMA PLUS
Codici / Codes:

34220, 34221, 34222, 34223, 34224, 34225 ; 34252, 34253, 34254, 34255; 34250

Modello / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks
Codici / Codes:

34424; 34425, 34426, 34427, 34428, 34429

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Organismo Notificato n. 0476
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CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Modello / Model:

Palloni rianimatori in silicone / Kit Palloni rianimatori in silicone adulti / Silicone resuscitators / Adult silicone resuscitators kit
Codici / Codes:

34245, 34246, 34247; 34248, 34277, 34249 ; 34244

Modello / Model:

Reservoir monouso (sacche ossigeno) e valvola / Oxygen reservoir and valve
Codici / Codes:

34257; 34258; 34275; 34279

Modello / Model:

Valvola PEEP e adattatore / Valvola antireflusso e posteriore / Peep valve and adapter / Non-rebreathing valve and intake valve
Codici / Codes:

34227 ; 34228 ; 34259 ; 34256

Tipologia / *Medical Devices:*
Dispositivi per terapia termica / *Thermic therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1403

Modello / Model:

Ghiaccio istantaneo TNT / PE / TNT / PE instant ice cold pack
Codici / Codes:

34110 ; 34111

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Data:25/05/2021 10:15:10

Organismo Notificato n. 0476
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CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Modello / Model:

Kit per rimozione sutura / kit procedurale sutura / Suture removal pack / Suture procedure pack

Codici / Codes:

38950 ; 38951

Tipologia / *Medical Devices:*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Modello / Model:

Forbici per bende di Lister / Forbici chirurgiche standard / Lister bandage scissors / Standard surgical scissors

Codici / Codes:

388xx

Modello / Model:

Pinza di Magill / Pinza di Hartmann per orecchio / Magill forceps / Hartmann ear forceps

Codici / Codes:

388xx

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Modello / Model:

Forbici di Mayo / Forbici di Metzenbaum / Forbici Iris / Forbice ombelicale / Forbice per chirurgia orecchio di Bellucci / Pinze per medicazione standard / Pinze di Hunter-Splinter / Pinze emostatiche di Adson / Pinze emostatiche Halstead-Mosquito / Pinza per dissezione McIndoe / Pinze di Pean / Pinza di Spencer-Wells / Pinza portatamponi di Foerster / Portaghi di Hegar- Mayo / Portaghi di Crile-Wood / Mayo scissors / Metzenbaum scissors / Iris scissors / Umbilical scissors / Bellucci ear scissors / Standard dressing forceps / Hunter-Splinter forceps/ Adson haemostatic forceps/ Halstead-Mosquito dissection forceps / McIndoe dissection forceps/ Pean forceps / Spencer-Wells forceps/ Foerster polypus forceps/ Hegar-Mayo needle holder / Crile-Wood needle holder

Codici / Codes:

388xx ; 389xx

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
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Data:25/05/2021 10:16:08

Organismo Notificato n. 0476
Notified Body nr. 0476

BeneFusion eSP

Syringe Pump

Data Sheet

Physical Specifications

Weight	≤ 1.6kg
Size	≤ 257x 150 x73mm
Screen	3.5 inch touchscreen TFT color LCD, 200x400 pixels
Brightness	1-8 levels, adjustable
Display	Infusion status (drug name, major infusion parameters, real-time pressure status) System status information (alarm information, infusion mode, battery status, relayed status, syringe brand or bed number)
Indicator on the door	Infusion status indicator

Parameters Specifications

Accuracy	≤ ±1.8%
Mode	Rate mode, Dose Mode, Dose Time Mode, Time mode, Sequential Mode, Intermittent Mode, Loading Dose Mode, Ramp Mode, Micro-infusion Mode Optional: TIVA Mode, PCA Mode, TCI Mode
Flow rate	0.01-2300ml/h
Increment	0.01ml/h (0.01-99.99ml/h), 0.1ml/h (100.0-999.9ml/h), 1ml/h (1000-2300ml/h)
Preset volume (VTBI)	0.01 ml - 9999.99 ml, increment: 0.01mL
Preset time	00:00:01-99:59:59
Accumulated volume	0.00 ml - 99999.99 ml
KVO	0.01 to 5.0ml/h, increment: 0.01ml/h
Purge rate	0.01-2300ml/h
Bolus rate	0.01-2300ml/h (automatic or manual)
Occlusion detection	50-1125mmHg (15 levels selectable, respectively are 50, 150, 225, 300, 375, 450, 525, 600, 675, 750, 825, 900, 975, 1050, 1125mmHg) default is 450mmHg, Pre-alarm: an alert will pop out when the pressure is continuously going up Auto-restart: On/Off, restart the infusion when the occlusion pressure is reduced. 4 units of pressure selectable: mmHg/kPa/bar/psi
Anti-bolus	Unexpected bolus reduced when the occlusion occurs
Dose rate units	ng/kg/min, ng/kg/h, ng/kg/24h, ug/kg/min, ug/kg/h, ug/kg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, g/kg/min, g/kg/h, g/kg/24h, mU/kg/min, mU/kg/h, mU/kg/24h, U/kg/min, U/kg/h, U/kg/24h, kU/kg/min, kU/kg/h, kU/kg/24h, EU/kg/min, EU/kg/h, EU/kg/24h, mmol/kg/min, mmol/kg/h, mmol/kg/24h, mol/kg/min, mol/kg/h, mol/kg/24h, mcal/kg/min, mcal/kg/h, mcal/kg/24h, cal/kg/min, cal/kg/h, cal/kg/24h, kcal/kg/min, kcal/kg/h, kcal/kg/24h, mEq/kg/min, mEq/kg/h, mEq/kg/24h
Auto-lock time	1 - 5 minutes selectable, ON/OFF switchable
Drug library	Up to 5000 drugs, 30 categories, support color-coding drug name
History log	Up to 3500 events
Volume collection	Available in 4 methods: 24h total, current total, period, timing volume, supports history rate review
DERS (Dose Error Reduction System)	Available, definition of dose limits, automatic alarms when reaching dose limits

Syringes

Compatibility	1/2/3/5/6/10/12/20/30/35/50/60ml, automatic recognition of syringe size

Alarms

Type	Audible and visual alarm
2 Levels	High: Occlusion/ Syringe Empty/ Syringe Disengaged/ Plunger Grippers Error/ Battery Depleted/ VTBI Complete/ KVO Finish/ Relay Invalid/ System Error/ No Syringe Low: Extension Line Detached/ KVO Running/ Battery in Use/ Battery Error/ CMS/eGW Disconnected/ Standby Time Expired/ Dock Connection Interrupted/ System Time Error/ Relay Invalid Soon/ Time Near End/ Reminder/ Low Battery/ Syringe Near Empty
Sound volume	1-8 levels selectable, default is level 6
Reminder	1-5 minutes selectable, ON/OFF switchable

Connectivity

Communication	Wired/wireless
USB	Support drug library import, patient data import/export, history record export, calibration data import/export
Multifunctional connector	RS232, nurse call connector, DC adapter
Integration	Connect with BeneFusion nCS infusion central station Connect with BeneVision Central Monitoring System

Battery

Operating time	≥ 5 hours at 5ml/h (≥ 11 hours at 5ml/h for smart battery)
Charging time	≤ 5 hours to full capacity (≤ 6 hours for smart battery)

Power Supply

Voltage 100-240 V~, frequency 50/60Hz, current 0.5-0.21A

Work Environment

Temperature	5-40ºC for operating, -30-70 ºC for storage
Relative humidity	15-95% for operating, 10-95% for storage
Atmosphere pressure	57.0-107.4 kPa for operating, 16.0-107.4 kPa for storage
Classification	Type CF, Class I, IP33
Stackability	Supported with stack rack, maximum of 3 pumps can be stacked

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P/N: ENG-BeneFusion eSP Datasheet-210285x2P-20201125

mindray

Declaration of Conformity CE 0123

Manufacturer: Shenzhen Mindray Scientific Co., Ltd.

6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block, Guangming District,

518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg, Germany

Product:	*Infusion pump (Including Accessories)*	*Syringe pump (Including Accessories)*	*Infusion supervision system (Including Accessories)*
Model:	*BeneFusion nVP* *BeneFusion nVP ex* *BeneFusion nVP Neo* *BeneFusion eVP* *BeneFusion eVP ex* *BeneFusion eVP Neo*	*BeneFusion nSP* *BeneFusion nSP ex* *BeneFusion nSP Neo* *BeneFusion eSP* *BeneFusion eSP ex* *BeneFusion eSP Neo*	*BeneFusion nDS* *BeneFusion nDS ex* *BeneFusion eDS* *BeneFusion eDS ex*
GMDN Code:	*13215*	*13217*	*36179*
MD Code:	*MD 1101*	*MD 1101*	*MD 1111*

Classification: IIb（According to Rule 11 of MDD Annex IX）

Conformity Assessment Route: MDD Annex Ⅱ excluding (4)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device，as amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Notified Body: TÜV SÜD Product Service GmbH

	Ridlerstraße 65
	80339 München, Germany
Notified Body No. :	0123
Place, Date of Issue:	Shenzhen, 2023.3.14
Signature:	Bai Yanhong
Name of Authorized Signatory:	**Bai yanhong**
Position Held in Company:	Manager, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V2.0

Product:	Infusion pump
Model:	BeneFusion nVP, BeneFusion nVP ex, BeneFusion nVP Neo BeneFusion eVP, BeneFusion eVP ex, BeneFusion eVP Neo

Applied Standards:

EN 60601-2-24:2015	Medical electrical equipment -- Part 2-24: Particular requirements for the safety of infusion pumps and controllers
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-8:2006+A1:2012/ EN 60601-1-8:2007/A1:2013	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 60601-1-2:2015	Medical Electrical Equipment - Part 1-2 General Requirements for Safety - Collateral Standard: Electromagnetic compatibility-Requirements and tests
EN ISO 20417: 2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1: 2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer- Part 1: General requirements
EN 1789: 2020	Medical vehicles and their equipment - Road ambulances

Attachment of Declaration of Conformity: Applied Standards List-V2.0

Product:	Syringe pump
Model:	BeneFusion nSP, BeneFusion nSP ex, BeneFusion nSP Neo BeneFusion eSP, BeneFusion eSP ex, BeneFusion eSP Neo

Applied Standards:

EN 60601-2-24:2015	Medical electrical equipment -- Part 2-24: Particular requirements for the safety of infusion pumps and controllers
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-8:2006+A1:2012/ EN 60601-1-8:2007/A1:2013	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 60601-1-2:2015	Medical Electrical Equipment - Part 1-2 General Requirements for Safety - Collateral Standard: Electromagnetic compatibility-Requirements and tests
EN ISO 20417: 2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1: 2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer- Part 1: General requirements
EN 1789: 2020	Medical vehicles and their equipment - Road ambulances

Attachment of Declaration of Conformity: Applied Standards List-V2.0

Product:	Infusion supervision system
Model:	BeneFusion nDS, BeneFusion nDS ex BeneFusion eDS, BeneFusion eDS ex

Applied Standards:

EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN60601-1-8:2007/A11 :2017	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
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IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 002584 0006 Rev. 02

Manufacturer:

Shenzhen Mindray Scientific Co., Ltd.
6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Infusion pump,
Syringe pump,
Infusion supervision system

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 002584 0006 Rev. 02

Report No.: SH20115102

Valid from: 2020-11-04
Valid until: 2024-05-26

Date, 2020-11-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Cum folositi Testele Accu-Chek Active:

- Asigurati-va ca aveti mainile curate si uscate.
- Luati un test din tub si inchideti imediat capacul. Glucometrul va porni automat dupa introducerea testului in fanta pentru teste (in directia sagetilor).
- Dupa o scurta verificare a afisajului si confirmarea numarului de cod (care corespunde cu numarul de cod de pe tubul cu teste), pe display apar simbolurile picaura de sange si testul. Aplicati o picatura de sange in zona verde de pe test si apoi indepartati degetul. Rezultatele vor fi afisare dupa 5 secunde.
- Glucometrul se va opri automat prin indepartarea testului. Rezultatul va fi stocat in memorie impreuna cu data si ora.

Testele Accu-Chek Active sunt usor de manevrat si permit dozarea in afara glucometrului.

- **Esantion mic**

Testele Accu-Chek Active necesita doar o cantitate mica de sange pentru a efectua un test de glucoza - doar 1-2µl de sange.

- **Actiune capilara**

Actiunea capilara atrage sange in banda pentru o testare rapida si de incredere a glicemiei.

- **Dozare in afara glucometrului**

Sangele poate fi aplicat pe test in afara glucometrului permitand o mai mare flexibilitate si este util in mod special persoanelor care au o problema cu dexteritatea.

Testele Accu-Chek Active se utilizeaza impreuna cu glucometrul Accu-Chek Active.

EG-Konformitätserklärung / EC Declaration of Conformity

Hersteller / **Manufacturer:** Roche Diabetes Care GmbH

Adresse / **Address:**
Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Roche Diabetes Care GmbH erklärt unter seiner alleinigen Verantwortung, dass das Produkt / die Produktfamilie
Roche Diabetes Care GmbH declares under its sole responsibility that the product / family of products

Accu-Chek® Active Blutglukose Überwachungssystem, bestehend aus:
Accu-Chek® Active Blood Glucose Monitoring System, consisting of:

Produktname / **Product name:**	Katalognummer / **Catalog Number:**
Accu-Chek® Active [Model GU] mg/dL *Meter*	**06658008**
Accu-Chek® Active [Model GB] mg/dL *Meter*	**07135114**
Accu-Chek® Active [Model GU] mmol/L *Meter*	**06657982**
Accu-Chek® Active [Model GB] mmol/L *Meter*	**07135122**

Beschreibung / **Description:**

Das Accu-Chek® Active Blutglukose Messgerät dient zusammen mit dem Accu-Chek® Active Teststreifen zur Überwachung der Blutglukosekonzentration im menschlichen Blut.
Das Blutglukoseüberwachungssystem ist sowohl für den Patientenselbsttest als auch für die professionelle Anwendung geeignet.
The Accu-Chek® Active blood glucose meter is intended to be used for quantitative blood glucose tests in human blood and is intended to be used together with Accu-Chek® Active test strips.
The blood glucose monitoring system is suitable for patient self-testing and for professional use.

Roche Diabetes Care GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Produktname / **Product name:**	Katalognummer / **Catalog Number:**	
Accu-Chek® Active *Test Strips*	**06656846**	(10 tests)
Accu-Chek® Active *Test Strips*	**07124210**	(10 tests)
Accu-Chek® Active *Test Strips*	**06656803**	(25 tests)
Accu-Chek® Active *Test Strips*	**07124155**	(25 tests)
Accu-Chek® Active *Test Strips*	**06656757**	(50 tests)
Accu-Chek® Active *Test Strips*	**07124112**	(50 tests)
Accu-Chek® Active *Test Strips*	**06656854**	(2 x 50 tests)
Accu-Chek® Active *Test Strips*	**07124287**	(2 x 50 tests)
Accu-Chek® Active *Test Strips*	**06887546**	(12x 50 tests)
Accu-Chek® Active *Test Strips*	**07124279**	(12x 50 tests)

Beschreibung / **Description:**

Der Accu-Chek® Active Teststreifen dient zusammen mit einem Accu-Chek® Active Blutglukose Messgerät zur Überwachung der Blutglukosekonzentration im menschlichen Blut.
Das Blutglukoseüberwachungssystem ist sowohl für den Patientenselbsttest als auch für die professionelle Anwendung geeignet.
The Accu-Chek® Active test strip is intended to be used for quantitative blood glucose tests in human blood and is intended to be used together with Accu-Chek® Active blood glucose meters.
The blood glucose monitoring system is suitable for patient self-testing and for professional use.

Produktname / **Product name:**	Katalognummer / **Catalog Number:**
Accu-Chek® Active *Control*	**03146324**

Beschreibung / **Description:**

Kontrolllösungen zur Funktionskontrolle von Accu-Chek® Active Blutglukose Messgeräten und Teststreifen.
Control solutions for carrying out performance checks on Accu-Chek® Active blood glucose monitors and test strips.

auf das / die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 über In-Vitro-Diagnostika entspricht. Gemäß Artikel 9, Absatz (3) a) der EG-Richtlinie 98/79/EG wurde für die oben aufgeführten IVD Produkte aus Anhang II, Liste B das Konformitätsbewertungsverfahren gemäß Anhang IV der Richtlinie unter Beteiligung der Benannten Stelle LRQA mit der Nummer 0088 angewandt.
to which this declaration relates, complies with the EC Directive 98/79/EC of October 27, 1998 on in vitro diagnostic medical devices. According to Article 9, Section (3) a) of the EC Directive 98/79/EC the above mentioned IVD devices are considered as Annex II, List B and the conformity assessment procedure using Annex IV with the involvement of LRQA (NB 0088) as the Notified Body was followed.

Die oben aufgeführten Produkte werden in verschiedenen Verpackungskonfigurationen sowie in Kombination mit anderen Produkten von Roche Diabetes Care GmbH, als Kit oder Set bezeichnet, in den Verkehr gebracht.

The above listed products are brought on the market in several package configurations as well as in combination with other products from Roche Diabetes Care GmbH, named Kit or Set.

Die Accu-Chek Active System Komponenten sind in folgenden Kits enthalten:
The Accu-Chek Active system components are packed into the following kits:

Accu-Chek Active Kits

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
06656897021	Accu-Chek® Active [Model GU] mg/dL Kit	06583202001 Accu-Chek® Active [Model GU] mg/dL Meter (Bulk) 06656846190 Accu-Chek Active test strip (10 tests) 05181186001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 Lancets)
06656897200		
06656897037	Accu-Chek® Active [Model GU] mg/dL Kit	06583202001 Accu-Chek® Active [Model GU] mg/dL Meter (Bulk) 06656846047 Accu-Chek Active test strip (10 tests) 05864810001 Accu-Chek FastClix Lancing Device 05208629001 Accu-Chek FastClix (17 Lancets)
06656919021	Accu-Chek® Active [Model GU] mmol/L Kit	06583130001 Accu-Chek® Active [Model GU] mmol/L Meter (Bulk) 06656846190 Accu-Chek Active test strip (10 tests) 05181186001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 Lancets)
07133766021	Accu-Chek® Active [Model GB] mg/dL Kit	06993770001 Accu-Chek® Active [Model GB] mg/dL Meter (Bulk) 07207506190 Accu-Chek Active test strip (10 tests) 05181186001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 Lancets)
07133766078		
07133766200		
07133766037	Accu-Chek® Active [Model GB] mg/dL Kit	06993770001 Accu-Chek® Active [Model GB] mg/dL Meter (Bulk) 07124210047 Accu-Chek Active test strip (10 tests) 05864810001 Accu-Chek FastClix Lancing Device 05208629001 Accu-Chek FastClix (17 Lancets)
07133766049	Accu-Chek® Active [Model GB] mg/dL Kit	06993770001 Accu-Chek® Active [Model GB] mg/dL Meter (Bulk) 07207506190 Accu-Chek Active test strip (10 tests) 05864810001 Accu-Chek FastClix Lancing Device 05208629001 Accu-Chek FastClix (17 Lancets)
07135076021	Accu-Chek® Active [Model GB] mmol/L Kit	06993761001 Accu-Chek® Active [Model GB] mmol/L Meter (Bulk) 07207506190 Accu-Chek Active test strip (10 tests) 05181186001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 Lancets)
07135076045		
07135076227		
07135076015		
07444141037	Accu-Chek® Active [Model GB] mg/dL Set	06993770001 Accu-Chek® Active [Model GB] mg/dL Meter (Bulk) 05181186001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 lancets)
07444141191		
07444141200		

06656919032	Accu-Chek® Active [Model GU] mmol/L Set	06583261001	Accu-Chek® Active [Model GU] mmol/L Meter (Bulk)
		05181186001	Accu-Chek Softclix Lancing Device
07135092032	Accu-Chek® Active [Model GB] mmol/L Set	06993788001	Accu-Chek® Active [Model GB] mmol/L Meter (Bulk)
		05181186001	Accu-Chek Softclix Lancing Device

Die in den Kits und Sets enthaltenen oben aufgeführten Medizinprodukte entsprechen den Forderungen der EG-Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte, geändert durch die EG-Richtlinie 2007/47/EG vom 5. September 2007; gemäß Anhang II der Richtlinie als Konformitätsbewertungsverfahren unter Beteiligung der Benannten Stelle LRQA mit der Nummer 0088.

The above mentioned medical devices contained in the Kits and Sets comply with the EC Directive 93/42/EEC of June 14, 1993 on medical devices, as amended by EC Directive 2007/47/EC of September 5, 2007 using Annex II as the conformity assessment procedure with the involvement of LRQA (NB 0088) as the Notified Body.

Diese EG Konformitätserklärung ist für alle oben aufgeführte Produkte gültig, die ab dem 26. Oktober 2018 in Verkehr gebracht werden.
This EC Declaration of Conformity is valid for all the above mentioned products placed on the market beginning of 26. October 2018.

Kontaktadresse / **Contact address:**

Roche Diabetes Care GmbH
Abt. Qualitätsmanagement, DCPQ
Sandhofer Strasse 116
68305 Mannheim
Germany
Telefax: +49 621/759 3801

Mannheim, 26. Oktober 2018

Roche Diabetes Care GmbH

i.V. / On behalf of the company

Dr. Alexander Rügner

Leiter Regulatory Affairs IDS and OUS submission
Head of Regulatory Affairs IDS and OUS submission

i.V. / On behalf of the company

Dr. Thomas Schmidt

Leiter Qualität Diabetes Care Systeme
Head of Quality Diabetes Care Systems

BeneFusion eVP

Infusion Pump

Data Sheet

Physical Specifications

Weight	≤ 1.7kg
Size	≤ 210x 140 x73mm
Screen	3.5 inch touchscreen, TFT color LCD, 200x400 pixels
Brightness	1-8 levels, adjustable
Display	Infusion status (drug name, infusion parameters, real-time in-line pressure) System status information (infusion mode, IV set brand or bed number, alarm symbol, battery status, network status, relayed status, and system time)
Indicator on the door	Infusion status indicator

Parameters Specifications

Accuracy	≤ ±4.5 % (for recommended sets)
Mode	Rate mode, Dose Mode, Dose Time Mode, Time mode, Sequential Mode, Intermittent Mode, Loading Dose Mode, Ramp Mode, Micro-infusion Mode, Drip Mode
Application supported	IV drug infusion, enteral nutrition feeding, and blood transfusion
Flow rate	0.10ml/h - 2300ml/h (0.10-2000ml/h for blood transfusion
Increment	0.01ml/h (0.10-99.99ml/h), 0.1ml/h (100-999.9ml/h), 1ml/h (1000-2300ml/h)
Preset volume (VTBI)	0.10 – 9999.99ml (increment: 0.01ml)
Preset time	00:00:01 – 99:59:59
Accumulated volume	0.00 - 99999.99 ml
KVO	0.1 - 5.0ml/h, increment: 0.01ml/h
Purge rate	0.1 - 2300ml/h
Bolus rate	0.1 - 2300ml/h (automatic or manual)
Occlusion detection	50-1125mmHg (15 levels selectable, respectively are 50, 150, 225, 300, 375, 450, 525, 600, 675, 750, 825, 900, 975, 1050, 1125mmHg) Default is 450 mmHg Pre-alarm: an alert will pop out when the pressure is continuously going up Auto-restart: On/Off, restart the infusion when the occlusion pressure is reduced. 4 units of pressure selectable: mmHg/kPa/bar/psi
Anti-bolus	Unexpected bolus reduced when the occlusion occurs
Dose rate units	ng/kg/min, ng/kg/h, ng/kg/24h, ug/kg/min, ug/kg/h, ug/kg/24h, mg/kg/min, mg/kg/h, mg/kg/24h, g/kg/min, g/kg/h, g/kg/24h, mU/kg/min, mU/kg/h, mU/kg/24h, U/kg/min, U/kg/h, U/kg/24h, kU/kg/min, kU/kg/h, kU/kg/24h, EU/kg/min, EU/kg/h, EU/kg/24h, mmol/kg/min, mmol/kg/h, mmol/kg/24h, mol/kg/min, mol/kg/h, mol/kg/24h, mcal/kg/min, mcal/kg/h, mcal/kg/24h, cal/kg/min, cal/kg/h, cal/kg/24h, kcal/kg/min, kcal/kg/h, kcal/kg/24h, mEq/kg/min, mEq/kg/h, mEq/kg/24h
Air bubbles detection	6 levels selectable: 15/50/100/250/500/800μL, accumulate air: 0.1-1.0ml/15min
Auto-lock time	1 - 5 minutes selectable, ON/OFF switchable
History log	up to 3500 events
Volume collection	available in 4 methods: 24h total, current total, period, timing volume, support history rate review
Drug library	Up to 5000 drugs, 30 categories, support color-coding drug name
DERS (Dose Error Reduction System)	Available, definition of dose limits, automatic alarms when reaching dose limits

IV administration sets

Compatibility	universal IV sets

Alarms

Type	Audible and visual alarm
2 Levels	High: Air in Line/ Accumulated Air/ Empty/ Drop Error/ Upstream Occlusion/ Downstream Occlusion/ Infusion Set Disengaged/ No Infusion Tube/ Infusion Set Error /No Drop Sensor/ Battery Depleted/ VTBI Complete/ KVO Finish/ Relay Invalid/ System Error Low: KVO Running/ Battery in Use/ Battery Error/ CMS/eGW Disconnected/ Standby Time Expired/ Dock Connection Interrupted/ System Time Error/ Relay Invalid Soon/ Time Near End/ Reminder/Low Battery
Sound volume	1-8 levels selectable, default is level 6
Reminder	1-5 minutes selectable, ON/OFF switchable

Connectivity

Communication	Wired/wireless
USB	Support drug library import, patient data import/export, history record export, calibration data import/export
Multifunctional connector	RS232, nurse call connector, DC adapter
Integration	Connect with BeneFusion nCS infusion central station Connect with BeneVison Central Monitoring System (CMS)

Battery

Operating time	≥ 5 hours at 25ml/h (≥ 11 hours at 25ml/h for smart battery)
Charging time	≤ 5 hours to full capacity (≤ 6 hours for smart battery)

Power Supply

Voltage 100-240 V~, frequency 50/60Hz, current 0.5-0.21A

Work Environment

Temperature	5-40ºC for operating, -30-70 ºC for storage
Relative humidity	15-95% for operating, 10-95% for storage
Atmosphere pressure	57.0-107.4 kPa for operating, 16.0-107.4 kPa for storage
Classification	Type CF, Class I, IP33
Stackability	Supported with stack rack, maximum of 3 pumps can be stacked

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China
Tel: +86 755 8188 8998 Fax: +86 755 26582680
E-mail: intl-market@mindray.com www.mindray.com

P/N: ENG-BeneFusion eVP Datasheet-210285x2P-20201125

mindray

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 002584 0005 Rev. 05

Holder of Certificate: **Shenzhen Mindray Scientific Co., Ltd.**
6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development,
Production and Distribution of
Infusion pump,
Syringe pump,
Enteral feeding pump,
Infusion supervision system**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 002584 0005 Rev. 05

Report No.: SH22115102

Valid from: 2023-05-19
Valid until: 2026-05-18

Date, 2023-05-08

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 002584 0005 Rev. 05

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Shenzhen Mindray Scientific Co., Ltd.
6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

FUTURA ECO CASE - beige - empty

Code:	**34132**
Category:	**First aid bags, cases and cabinets**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**No medical device**

EAN13: **8056389236051**

Description:

FUTURA ECO CASE - beige

First eco-sustainable case, made of Compound PP/ Wood Flour (WPC-Wood Plastic Compound) with vegetable charges between 30-40%.
It maintains all the qualities of wood, PP resistance and preserves the environment.
Equipped with wall support, transport handle and closure with 2 rotating clips.

Size: 250 x190xh 90 mm.

100% recycled material.

Made in Italy.

SPENCER 122

Foldable stretcher

Spencer 122 field stretchers are devices for lifting and carrying people which are also suitable for parking in field rescue conditions. If they are not equipped with supports, they can be parked using the Porta Stock stand.

Specific features
Extremely lightweight and durable structure
Very low storage space required
Lengthwise and breadthwise foldable
Easy to clean sheet

Technical data	
Length when open (mm)	2010 ± 10 mm
Length when folded (mm)	1000 ± 10 mm
Width when open (mm)	550 ± 5 mm
Width when folded (mm)	400
Height when open (mm)	140
Height when folded (mm)	170 ± 5 mm
Weight (kg)	6.5 ± 0.3 kg
Capacity (kg)	170
Gripping points (no.)	4
Support feet (no.)	4
Materials	Al, Steel, PVC

Standard equipment
STX 598 Restraint belts 2 pcs

Class I MD compliant with UE Reg. 2017/745	
SPENCER 122 - FOUR FOLD STRETCHER ORANGE	CE
ST00122A	
CND Classification	V9099
Registration number	172360

Bureau Veritas Certification

ME.BER. S.R.L.

Via Langhirano, 270 - 43124 PARMA (PR) - Italy

Certified site:

Via Langhirano, 270 - 43124 PARMA (PR) - Italy

Bureau Veritas Italia S.p.A. certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 13485:2016

Scope of certification

Design, manufacturing and service of active devices for patient positioning and transport. Trade of general non-implantable active and non-active medical devices for first aid and emergency.

Certificate issued in accordance with the Technical Regulation ACCREDIA DT 02-DC Rev.00

Original cycle start date by a different certification body:	**05-February-2007**
Expiry date of previous cycle:	**01-February-2022**
Certification / Recertification Audit date:	**31-January-2022**
Certification / Recertification cycle start date:	**02-February-2022**
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	**01-February-2025**

Certificate No.: **IT313613** Version: **1** Issue Date: **02-February-2022**

GIORGIO LANZAFAME - Local Technical Manager

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 009A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC mutual Recognition Agreements

Certification body address:

Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.

To check the validity of this certificate please double click or scan QR CODE

Bureau Veritas Certification

ME.BER. S.R.L.

Via Langhirano, 270 - 43124 PARMA (PR) - Italy

Certified site:

Via Langhirano, 270 - 43124 PARMA (PR) - Italy

Bureau Veritas Italia S.p.A. certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

Design, manufacturing and service of active devices for patient positioning and transport. Trade of general non-implantable active and non-active medical devices for first aid and emergency.
IAF: 17, 19, 29

Original cycle start date by a different certification body:	**05-February-2007**
Expiry date of previous cycle:	**01-February-2022**
Certification / Recertification Audit date:	**31-January-2022**
Certification / Recertification cycle start date:	**02-February-2022**
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	**01-February-2025**

Certificate No.: **IT313614** Version: **1** Issue Date: **02-February-2022**

GIORGIO LANZAFAME - Local Technical Manager

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 009A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC mutual Recognition Agreements

Certification body address:
Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.

To check the validity of this certificate please double click or scan QR CODE

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Certificate

No. Q5 033230 0033 Rev. 00

Holder of Certificate: **Spencer Italia s.r.l.**
Via Provinciale 12
43038 Sala Baganza (PR)
ITALY

Certification Mark:

Scope of Certificate: **Design and development, production of emergency equipment; Distribution of medical, emergency and rescue equipment with own and other brands**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 033230 0033 Rev. 00

Report No.: ITA 1683049

Valid from: 2021-11-09
Valid until: 2024-08-04

Date, 2021-11-09

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 033230 0033 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Spencer Italia s.r.l.
Via Provinciale 38, 43038 Sala Baganza (PR), ITALY

\Warehousing of medical, emergency and rescue equipment with own and other brands.

Spencer Italia s.r.l.
Via Provinciale 12, 43038 Sala Baganza (PR), ITALY

Design and development,, production of emergency equipment; Distribution of medical, emergency and rescue equipment with own and other brands

Spencer Italia s.r.l.
Via Petitot 4, 43038 Sala Baganza (PR), ITALY

Warehousing of medical, emergency and rescue equipment with own and other brands.

Spencer Italia srl
Via Lega dei Carrettieri 3, 43038 Sala Baganza (PR), ITALY

Warehousing and Distribution of medical, emergency and rescue equipment with own and other brands.

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®