M860

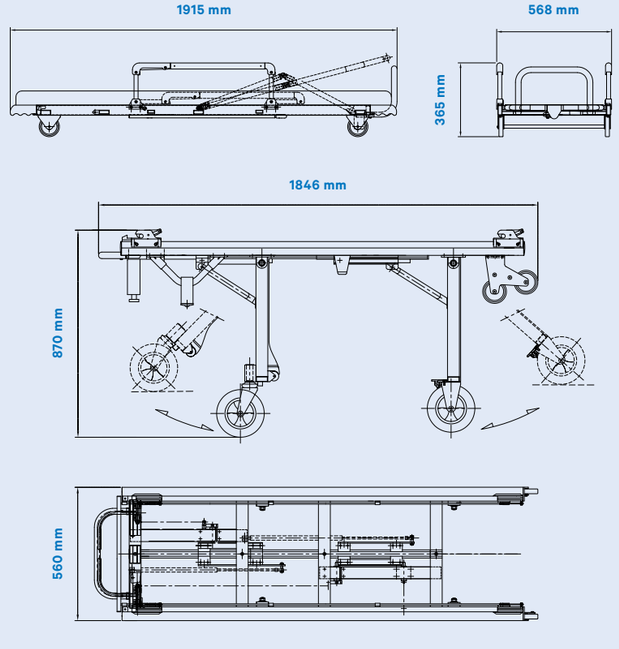
Carucior si targa – separabile

Digitally signed by Gorgan Vasile-Dan
Date: 2023.09.19 22:20:22 EEST
Reason: MoldSign Signature
Location: Moldova

EN 1865-1
10G

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

Certificate of Registration

Certificado de Conformidade

This is a Translation of PT01/00383

The Management System of

AUTO RIBEIRO, LDA

Rua São Caetano, 459 - 519
4411-701 CANELAS

has been assessed and certified as meeting the requirements of

NP EN ISO 9001:2015

For the following activities:

Conception, Transformation and Vehicles Selling, including Ambulances and their Equipment´s, Wheelchair Accessible Vehicles, Cash in Transit Vehicles, Prisoner Transport Vehicles, Passenger Vehicles and Home Care Vehicles.
Provision of vehicle and equipment repair services.

This certificate is valid from

Este certificado é valido desde

11 October 2021 until 5 October 2024

and remains valid subject to satisfactory surveillance audits

11 de Outubro de 2021 a 5 de Outubro de 2024, sujeito a auditorias de acompanhamento com resultados satisfatórios

Re certification audit due before 5 August 2024

Auditoria de Renovação a realizar antes de 5 de Agosto de 2024

Issue 12. Certified with SGS since June 2001

Versão 12. Certificado pela SGS desde Junho de 2001

The audit leading to this certificate commenced on 6 September 2021
A auditoria que levou à emissão deste certificado teve início em 6 de Setembro de 2021
Previous issue certificate validity date was until 5 October 2021
A data de validade do certificado anterior foi até 5 de Outubro de 2021

Authorized by
Autorizado por:

Luís Neves
Certification Management
Direção de Certificação

Luis Santos

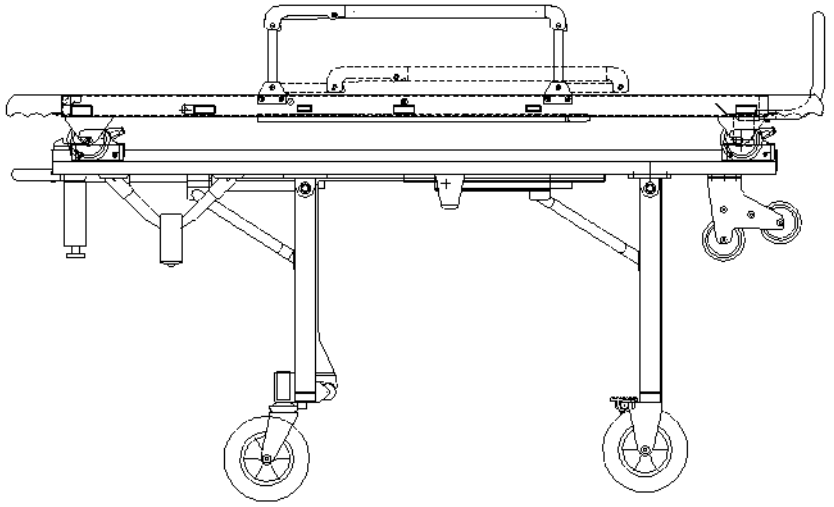
SGS ICS – Serviços Internacionais de Certificação
Pólo Tecnológico de Lisboa, 6 piso 0 – 1600-546 Lisboa
T: 217104200; F: 217157527

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
autoribeiro@autoribeiro.pt
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

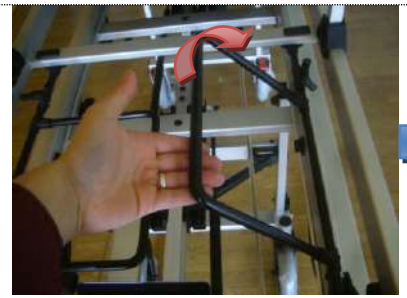
- Perform visual inspection every fifty cycles of utilization.
- Lubrication elements of mechanical function every six months with high viscosity lubricant
- Checking of tightness of binding elements of every three months. Proceed to ajust if necessary

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.

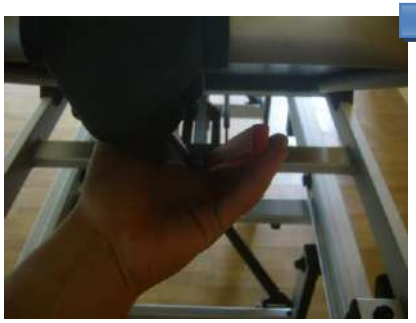
ADJUSTABLE BACKREST

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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4411-701 Canelas; Vila Nova de Gaia, Portugalia
Tel.: +351 227157100 , Fax: +351 2271244
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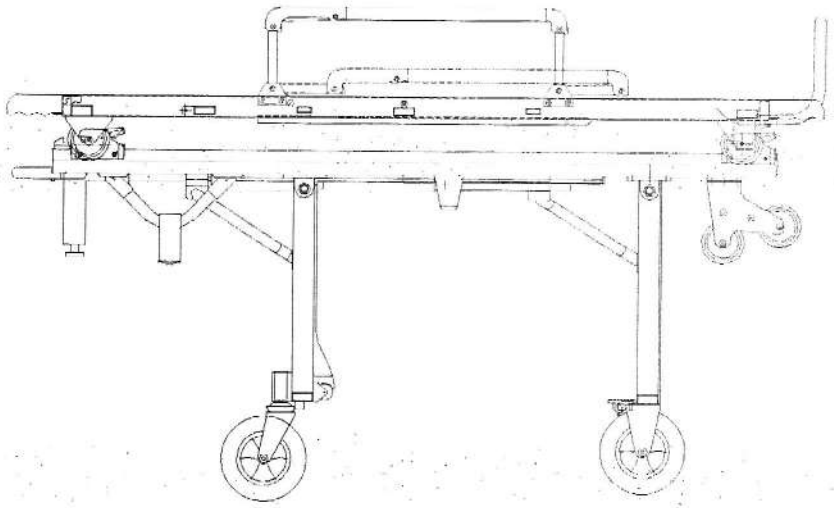
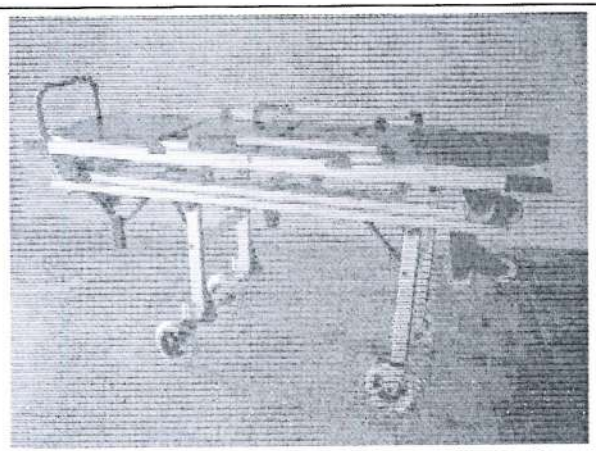
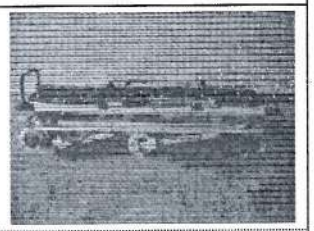


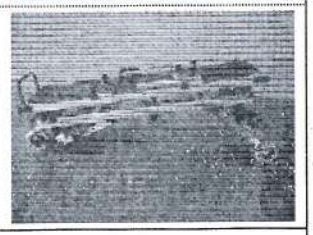
M860: Cărucior / targă - separabile

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.

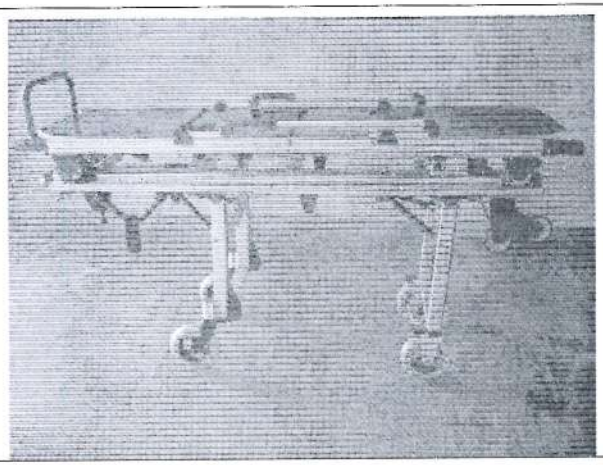
Vedere generală a echipamentului

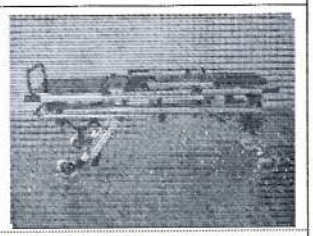


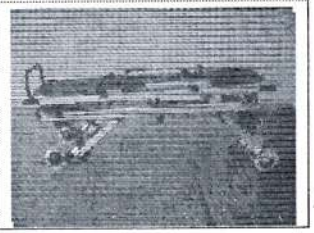




Vedere laterală a echipamentului

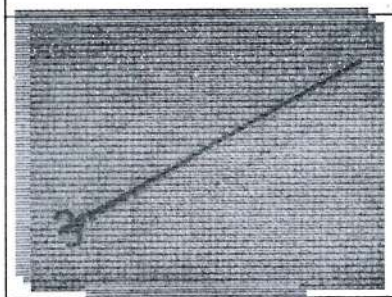




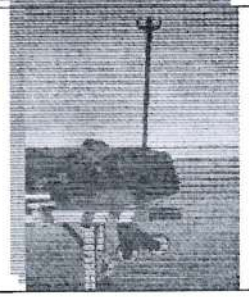


ACCESORII

Stâlp IV

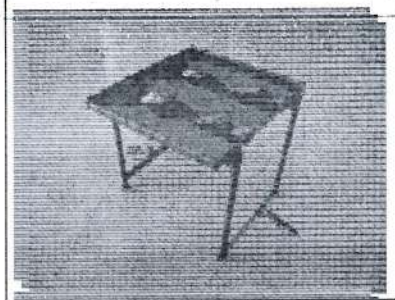


Suport perfuzii



Suportul perfuzii in utilizare

Tava pentru instrumente

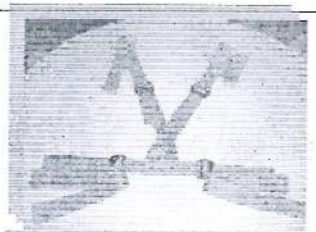


Tava pentru instrumente.

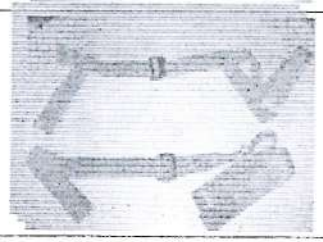
Tava pentru instrumente în uz.

ACESORII

Fixarea centurilor de fixare

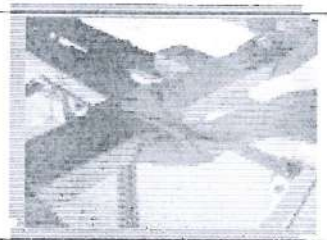


Centuri de fixare umăr

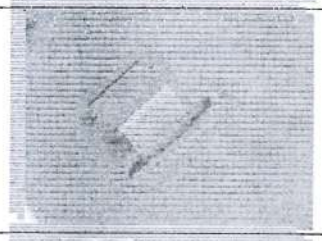


Centuri de fixare picioare și mijloc

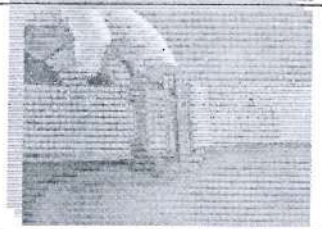
Montarea curelelor de fixare



1° - Legați curelele de fixare de barele interioare.

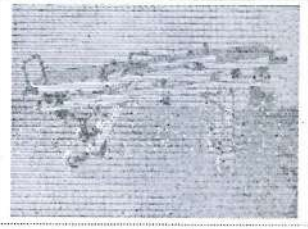


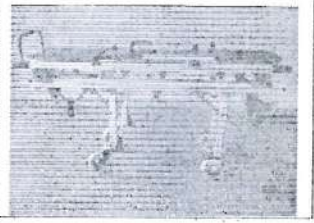
2° - Treceți curelele de fixare prin fantele de pe placă



3° - Cuplați cataramele.

Vedere de sus a echipamentului

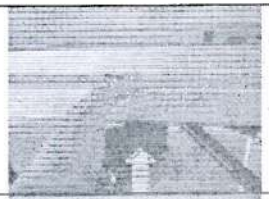
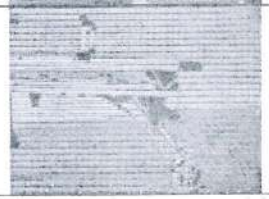




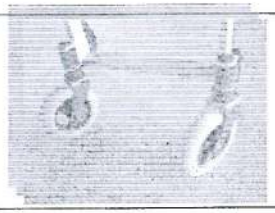
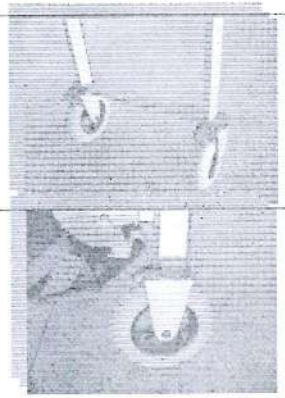
CARACTERISTICI:

- 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

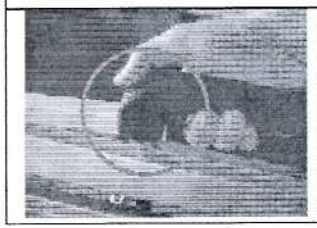
CONTROL PICIOR DIN FAȚĂ (poziția de mijloc)

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

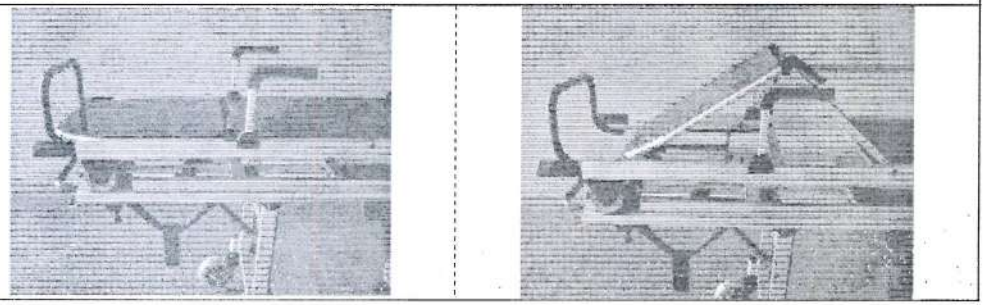
⚠

- 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

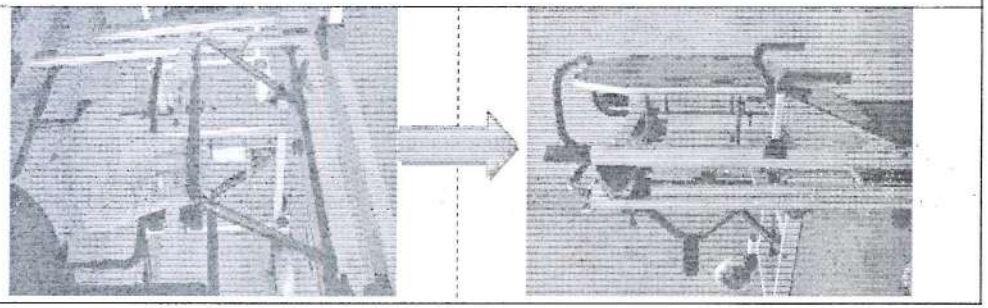
POZIȚIE REGLABILĂ A LABELOR

Labele pot fi fixate în trei poziții:

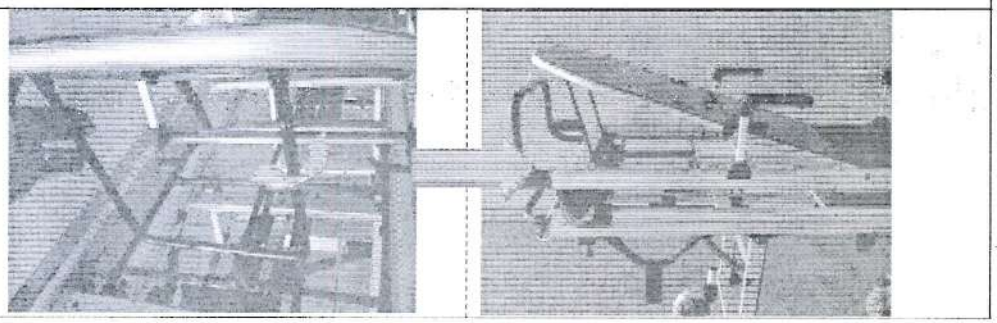
Repaus labe si genunchi flexati



Ridicare partea superioară pentru labe (16°)

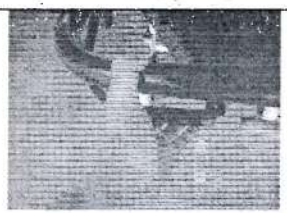


Ridicarea picioarelor



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.

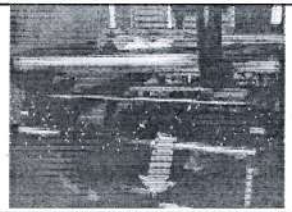
CONTROL PICIOR DIN FAȚĂ

Sistem de securizare

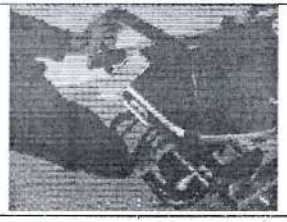
1° - Apăsați maneta din dreapta până când începe să se deplaseze și țineți-o apăsată.

CONTROL SISTEM DE BLOCARE TARGĂ

Sistem de securizare



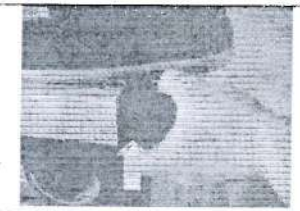
1° - Apăsați maneta din dreapta și țineți-o apăsată.



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

MÂNERE TELESCOPICE

Sistem de securizare

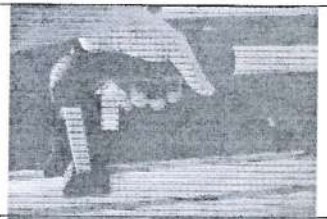


1º - Apăsați butonul cu degetul.

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

COBORÂRE BARE LATERALE

Sistem de securizare



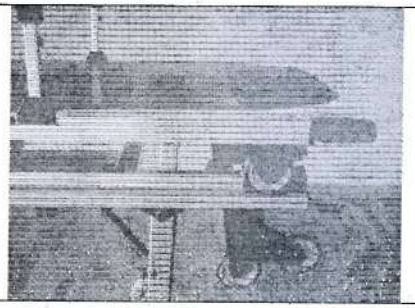
1º - Apăsați butonul cu mâna.

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

SPĂTAR REGLABIL

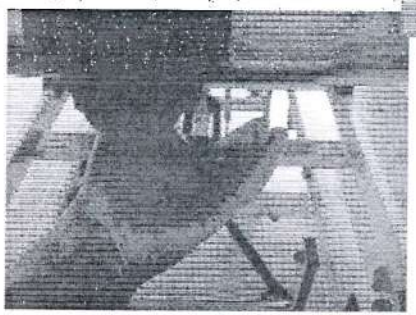
Spătarul poate fi reglat în mai multe poziții:

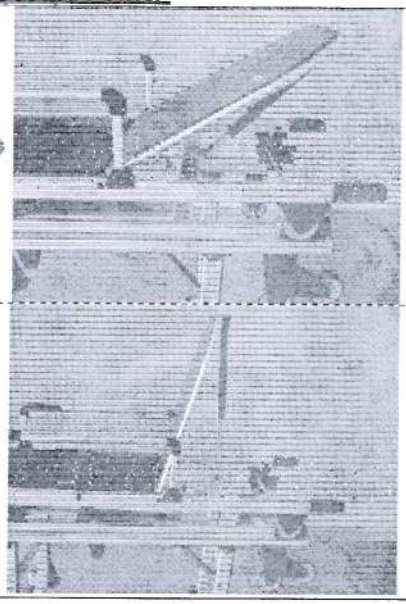
Poziția culcat pe spate



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**

Ergonomic Mattress

EN 597-1:1994

Color palette

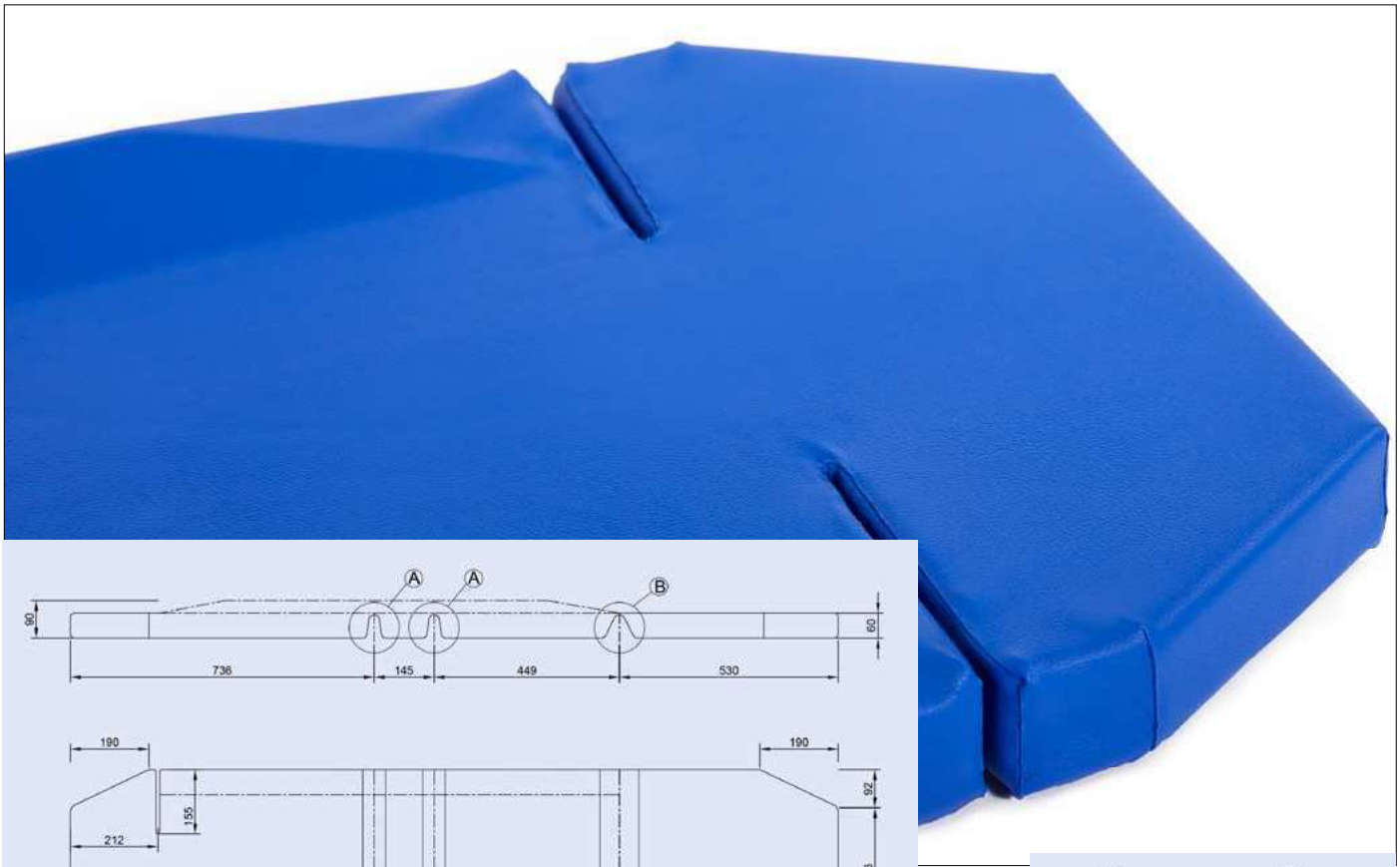
ARE Mattress Comfort on the way to recover

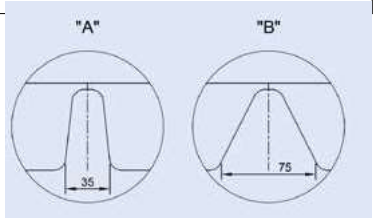
Compatible with all models AREquipment ,this 4 part ergonomic mattress was conceived specifically to be comfortable and to be safe.

- Recommended used in conjunction with Chest and Legs Patient Restraints
- No progressive smouldering or flaming ignition when tested in accordance with EN 597-1:1994
- The materials are not affected by disinfectants
- Easy-to-clean
- Comfortable
- Compatible with all models AREquipment

Dimensions

1880 x 510 mm





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NIF 500 434 980

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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		

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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
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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
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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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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.

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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

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.

TECHNICAL DATA SHEET

Item Code	Name
631	***Grey anodized anti trauma scoop stretcher with head/trunk in 1 pc***
631/G	***Yellow painted anti trauma scoop stretcher with head/trunk in 1 pc***

Dimensions [mm]	**Min. Length:**	**1670**
	MAX Length:	**2020**
	Folded Length:	**1200**
	Width:	**420**
	Height:	**70**
	Folded Height:	**90**
Used materials	**anodized Al**	
Weight [kg]	**9,5**	
MAX Load [kg]	**170**	
Declared use	**Transport, in horizontal position, of patients temporarily or permanently unable, whose pathologies are compatible**	
Conformity	**MDD 93/42/CEE - Class I Medical Device** **EN 1865-1 - EN 1789 Certified**	

Me.Ber. srl Unipersonale – Via Langhirano, 270 – 43124 Fontanini (PR) Italy
Tel. +39 0521 648770 – Fax +39 0521 648780 www.meber.it – info@meber.it

FIȘĂ TEHNICĂ

Codul produsului	***623***
Denumire	***DOUBLE PLUS - Imobilizator de cap ajustabil pentru targă lopată***

Dimensiuni [mm]	**Lățime totală: 400**
	Lățime atelă: 200
	Adâncime: 240
	Înălțime totală: Ajustabilă
	Înălțime atelă: 30
Materiale utilizate în fabricație	**Spumă E.V.A.** **Aluminiu** **Strat de vinil colorat** **Velcro®** **Polipropilenă** **Nailon**
Greutate [kg]	**0,5**
Interval de temperatură [°C]	**-5 ÷ +50**
Scop declarat	**Imobilizarea temporară a gâtului și a capului pentru pacienții pediatrici care prezintă traume cervicale**
Conformitate	**MDD 93/42/EEC - Clasa I Dispozitive Medicale**

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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**

TECHNICAL DATA SHEET

Item code	***623***
Name	***DOUBLE PLUS - Adjustable head immobilizer for scoop stretcher***

Dimensions [mm]	**Joined width:**	**400**
	Splint width:	**200**
	Depth:	**240**
	Joined height:	**Adjustable**
	Splint height:	**30**
Used materials	**Foam E.V.A.** **Aluminium** **Coloured vinyl coating** **Velcro®** **Polypropylene** **Nylon**	
Weight [kg]	**0,5**	
Temperature range [°C]	**-5 ÷ +50**	
Declared use	**Temporary immobilization of neck and head of paediatric patients struck by cervical traumas**	
Conformity	**MDD 93/42/EEC - Class I Medical Device**	

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Tel. 0521/648770 - Fax 0521/648780 - e-mail : contact@meber.it - info@meber.it
www.meber.it

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

DICHIARAZIONE DI CONFORMITÀ
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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*	**"DOUBLE PLUS" FERMACAPO ADATTABILE PER SCOOP ART. 623** ***"DOUBLE PLUS" ADJUSTABLE HEAD IMMOBILIZER FOR SCOOP STRETCHER ART. 623***
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*	**n.a.**

Fontanini, 01/11/2017

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

TANGO

Integrated pediatric and adult spine boards

Tango spine boards are devices designed to lift and immobilize patients with suspected spinal injuries.

Specific features
The integration of adult and pediatric spinal boards, offers unmatched versatility
Pediatric spinal board with differentiated occipital areas for the best adaptation to the anatomical characteristics of pediatric patients
The pediatric spinal board can be easily extracted from the adult one, ensuring fast rescue operations and minimizing storage space
The head immobilizer can easily placed thanks to strap bands

Technical data	
Spinal board dimensions	1830 x 445 x 55 mm
Number of handles	14
Pediatric spinal board weight	3 kg
Adult spinal board weight	8 kg
Weight of complete spinal board	11 kg
Tango load capacity	150 kg
Baby Go load capacity	30 kg
Pediatric spinal board dimensions	1190 x 320 x 45 mm
Pediatric spinal board number of handles	10
Materials	Polyethylene

Accessories	
ST02102B	Spine Pack – Carry bag
ST02106A	MARK UP – Permanent personalization system
ST02105A	Fix Board – 10 G Wall support for spinal board

Class I MD compliant with UE Reg. 2017/745	
TANGO ADULT AND PAEDIATRIC SPINE BOARD	CE
ST02140C	
CND Classification	V0804
Registration number	101670

Rev.0 (14/06/2021)
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:*	IT-MF-000027507
Medical Device/*Dispositivo Medico:*	TANGO ADULT AND PAEDIATRIC SPINE BOARD/ *TANGO TAVOLA SPINALE.PEDIATR.E ADULTO INTEGR.*
Code /*Codice:*	ST02140C
BASIC UDI-DI /*UDI-DI di base:*	805771123TAVOLESPINALITT
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, 11/01/2023

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)*

Italia

CERTIFICATO

Nr. 50 100 6189 Rev.006

SI ATTESTA CHE / *THIS IS TO CERTIFY THAT*

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

Spencer Italia s.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA PROVINCIALE 12
IT - 43038 SALA BAGANZA (PR)

SEDI OPERATIVE: **VEDI ALLEGATO 1** / *OPERATIONAL SITES:* ***SEE ANNEX 1***

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione, sviluppo e produzione di dispositivi per l'emergenza e funerario. Commercializzazione di prodotti per il settore medicale, emergenza, soccorso e funerario a marchio proprio e non (IAF 19, 14, 29)

Design, development and production of emergency and mortuary equipment. Distribution of medical, emergency rescue and mortuary equipment with own and other brands (IAF 19, 14, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità /*Validity*

Dal / From: **2021-08-05**

Al / To: **2024-08-04**

Andrea Coscia
Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione / *Issuing Date*

2021-08-05

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2006-10-03

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2021-08-04
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2021-08-04*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Italia

ALLEGATO 1 AL CERTIFICATO NR **50 100 6189 Rev.006**
ANNEX 1 *TO CERTIFICATE NO* ***50 100 6189 Rev.006***
pagina 1 di 1 / *page 1 of 1*

IL CERTIFICATO NR 50 100 6189 Rev.006 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N *50 100 6189 Rev.006 COVERS ALSO THE FOLLOWING OFFICES:*

Spencer Italia s.r.l.

VIA PROVINCIALE 12 **IT - 43038 SALA BAGANZA (PR)**	Progettazione, sviluppo e produzione di dispositivi per l'emergenza e funerario. Commercializzazione di prodotti per il settore medicale, emergenza, soccorso e funerario a marchio proprio e non *Design, development and production of emergency and mortuary equipment. Distribution of medical, emergency rescue and mortuary equipment with own and other brands*
VIA PETITOT 4 **IT - 43038 SALA BAGANZA (PR)**	Immagazzinamento di prodotti per il settore medicale, emergenza e soccorso a marchio proprio e non *Warehousing of medical, emergency and rescue equipment with own and other brands*
VIA LEGA DEI CARRETTIERI 3 **IT - 43038 SALA BAGANZA (PR)**	Immagazzinamento di prodotti per il settore medicale, emergenza e soccorso a marchio proprio e non *Warehousing and Distribution of medical, emergency and rescue equipment with own and other brands*
VIA PROVINCIALE 38 **IT - 43038 SALA BAGANZA (PR)**	Immagazzinamento di prodotti per il settore medicale, emergenza e soccorso a marchio proprio e non *Warehousing of medical, emergency and rescue equipment with own and other brands*

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 049A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità /*Validity*
Dal / From: **2021-08-05**
Al / To: **2024-08-04**

Andrea Coscia
Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione / *Issuing Date*
2021-08-05

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2006-10-03

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2021-08-04
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2021-08-04*

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"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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®

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

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

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

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
T: +43 (0)6452 7193 0 F: +43 (0)6452 7193 51
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
A-5550 Radstadt Austria
T: +43 (0)6452 7193 0 F: +43 (0)6452 7193 51
info@redvac.com www.RedVac.com

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

Radstadt · Loretostraße 4 – 8
Tel. +43-(0)6452-7193 0 · Fax 7193 51
e-mail: office@kohlbrat-bunz.com
www.kohlbrat-bunz.com

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

SIQ Ljubljana has issued an IQNet recognized certificate that the organization:

Kohlbrat & Bunz GmbH

Loretostrasse 4-8, 5550 Radstadt, Austria

has implemented and maintains a
Quality management System
for the following scope:

Development, production and distribution
of rescue-, positioning- and transport - systems

which fulfils the requirements of the following standard:

ISO 9001:2015

First issued on: **2018-09-25**
Expires on: **2021-09-25**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: **SI – Q-2121**

Alex Stoichitoiu
President of IQNet

Igor Likar
Managing Director of SIQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

SIQ

Certifikat / Certificate

for
Management System

Kohlbrat & Bunz GmbH

Loretostrasse 4-8, 5550 Radstadt, Austria

Development, production and distribution
of rescue-, positioning- and transport - systems

adequately operates and maintains a management system which meets the requirements of the standard

ISO 9001:2015

Certificate No. / Certification date
Q-2121 / 2018-09-25

Valid until: **2021-09-25**

Director of SIQ Ljubljana
Igor Likar

SIQ is a partner of IQNet

IAF

SLOVENSKA AKREDITACIJA
SIST EN ISO/IEC 17021-1
CB-001

SIQ Ljubljana, Tržaška cesta 2, 1000 Ljubljana, Slovenija

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

SNAS
Reg. No. 153/Q-011

TÜV SÜD
Slovakia

CERTIFICATE

TÜV SÜD Slovakia s.r.o.
Certification Body for Management Systems

Accredited by SNAS
Certificate on accreditation No. Q-011

certifies that

FERNO Slovakia

Ferno Slovakia s.r.o.
893
SK – 913 07 Bošáca
IČO: 35 809 400

has established and applies
a Quality Management System for

Development, production, repair and modification of transport and fixation equipment, medical devices.

An audit was performed, Report No. **0401/30/23/Q/AS/R5**
Proof has been furnished that the requirements
according to

STN EN ISO 9001:2016

are fulfilled. The certificate is valid from **2023-05-07** until **2026-05-06**

Certificate Registration No. **Q 0401-6**

TÜV SÜD

Bratislava, 2023-05-04

TÜV SÜD Slovakia s.r.o.
Certification Body for Management Systems
Member of Group TÜV SÜD
Jašíkova 6, 821 03 Bratislava

F-Q-019/2/6

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)*

Italia

CERTIFICATO

Nr. 50 100 6189 Rev.006

SI ATTESTA CHE / *THIS IS TO CERTIFY THAT*

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

Spencer Italia s.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA PROVINCIALE 12
IT - 43038 SALA BAGANZA (PR)

SEDI OPERATIVE: **VEDI ALLEGATO 1** / *OPERATIONAL SITES:* ***SEE ANNEX 1***

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione, sviluppo e produzione di dispositivi per l'emergenza e funerario. Commercializzazione di prodotti per il settore medicale, emergenza, soccorso e funerario a marchio proprio e non (IAF 19, 14, 29)

Design, development and production of emergency and mortuary equipment. Distribution of medical, emergency rescue and mortuary equipment with own and other brands (IAF 19, 14, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità /*Validity*

Dal / From: **2021-08-05**

Al / To: **2024-08-04**

Andrea Coscia
Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione / *Issuing Date*

2021-08-05

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2006-10-03

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2021-08-04
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2021-08-04*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Italia

ALLEGATO 1 AL CERTIFICATO NR **50 100 6189 Rev.006**
ANNEX 1 *TO CERTIFICATE NO* ***50 100 6189 Rev.006***
pagina 1 di 1 / *page 1 of 1*

IL CERTIFICATO NR 50 100 6189 Rev.006 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N *50 100 6189 Rev.006 COVERS ALSO THE FOLLOWING OFFICES:*

Spencer Italia s.r.l.

VIA PROVINCIALE 12 **IT - 43038 SALA BAGANZA (PR)**	Progettazione, sviluppo e produzione di dispositivi per l'emergenza e funerario. Commercializzazione di prodotti per il settore medicale, emergenza, soccorso e funerario a marchio proprio e non *Design, development and production of emergency and mortuary equipment. Distribution of medical, emergency rescue and mortuary equipment with own and other brands*
VIA PETITOT 4 **IT - 43038 SALA BAGANZA (PR)**	Immagazzinamento di prodotti per il settore medicale, emergenza e soccorso a marchio proprio e non *Warehousing of medical, emergency and rescue equipment with own and other brands*
VIA LEGA DEI CARRETTIERI 3 **IT - 43038 SALA BAGANZA (PR)**	Immagazzinamento di prodotti per il settore medicale, emergenza e soccorso a marchio proprio e non *Warehousing and Distribution of medical, emergency and rescue equipment with own and other brands*
VIA PROVINCIALE 38 **IT - 43038 SALA BAGANZA (PR)**	Immagazzinamento di prodotti per il settore medicale, emergenza e soccorso a marchio proprio e non *Warehousing of medical, emergency and rescue equipment with own and other brands*

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 049A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità /*Validity*
Dal / From: **2021-08-05**
Al / To: **2024-08-04**

Andrea Coscia
Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione / *Issuing Date*
2021-08-05

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2006-10-03

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2021-08-04
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2021-08-04*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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®

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

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:*	SED SPENCER EXTRICATION DEVICE/ *SED - SPENCER EXTRICATION DEVICE C/SACCA*
Code /*Codice:*	SR00111B
BASIC UDI-DI /*UDI-DI di base:*	805771123ESTRICATORICZ
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, 14/05/2022

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

Rev.0 (04/05/2021)
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Spencer Italia S.r.l. Sala Baganza (PR) Italia Tel. +39.0521.541111 Fax +39.0521.541222
www.spencer.it

RES-Q-SPLINT KIT

Vacuum splints – Kit 3 sizes with pump and bag

Res-Q-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
PVC sheet easy to clean
Separate channels avoid movement and accumulation of filling material, ensuring its better distribution making more effective the immobilization of the limb
Fast closure thanks to the integrated tear-off straps
Non-return valve characterized by large air passages allow to reach the desired vacuum level faster
Carry bag with handles and housing for pump on the rear side
The supplied pump is characterized by small size and high efficiency

Technical data	
Dimensions size S	560 x 460 ± 10 mm
Dimensions size M	490 x 380 x 700 ± 10 mm
Dimensions size L	750 x 540 x 900 ± 10 mm
Weight size S	295 ± 50 g
Weight size M	630 ± 50 g
Weight size L	1050 ± 50 g
Bag dimensions	550 x 410 x 160 ± 20 mm
Materials	PVC, Al, PS
Weight of the kit	3,16 ± 0,2 kg

QM22500A		
RES-Q-SPLINT - KIT 3 SIZES W/PUMP AND BAG		
SET consisting of the following MD compliant with UE Reg. 2017/745		
QM22530A – RES-Q-SPLINT SIZE S - VAC.SPL. WITH SEPAR. CHAMB.	Reg. n. 102933	CND V0804
QM22520A – RES-Q-SPLINT SIZE M - VAC.SPL. WITH SEPAR. CHAMB.	Reg. n. 102924	CND V0804
QM22510A – RES-Q-SPLINT SIZE L - VAC.SPL. WITH SEPAR. CHAMB.	Reg. n. 102852	CND V0804

Rev.0 (04/05/2021)
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:*	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)*

Centura pentru imobilizare pelviană SAM II

PENTRU STABILIZAREA FRACTURILOR PELVIENE APLICÂND FORȚA CORECTĂ

SE APLICĂ ÎN DOAR 3 PAȘI SIMPLI

SAM MEDICAL PRODUCTS®

800.818 4726 | sammedical.com

NSN #6515-01-509-6866 (OD Green)

MADE IN USA

PERFECȚIONATĂ

pentru a fi cel mai bun produs pentru pacienții dumneavoastră

„Invizibilă” pentru razele X,
Permite investigații radiologice
Fără îndepărtarea centurii*

Suprafață Velcro atât pe centură
cât și pe cureaua de fixare,
Pentru o montare facilă și rapidă

Aplicare rapidă: cureaua se introduce prin cataramă,
se trage până când catarama nu mai permite și se asigură.
Un sunet tip „click” oferă confimarea faptului că centura a
atins punctul optim și poate fi asigurată pe suprafața velcro,
pentru o aplicare corectă

Eficiență dovedită științific și clinic
în aplicarea forței corecte și sigure
pentru stabilizarea facturilor pelviene

Forța de frecare redusă exercitată
de glisorul posterior facilitează transferul

Materialul reutilizabil nu se întinde;
se poate curăța pentru utilizări ulterioare
cu orice soluție antimicrobiană sau detergent standard

Catarama Autostop patentată oferă
compresia corectă de fiecare dată,
eliminând nevoia de a „ghici” forța de aplicare.
Catarama asigură de asemenea menținerea compresiei corecte,
astfel încat centura nu poate fi strânsă mai mult decât este nevoie,
în nicio circumstanță

Dimensiunea standard se potrivește
pentru 98% din populația adultă

Partea frontală a centurii este îngustată
pentru a facilita cateterizarea urinară,
radiologia intervențională, fixarea exterioară
și intervențiile chirurgicale abdominale.

Design funcțional minimalist

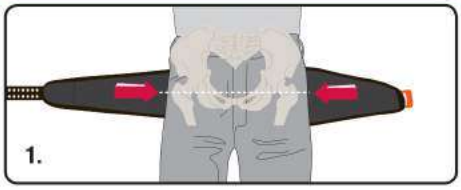
SAM este prima și singura centură de bazin circumferențială cu forță controlată.

Este dovedit științific în cadrul studiilor pentru condiții de siguranță că reduce în mod eficient și stabilizează fracturile pelviene de orice natură.
Centura pentru imobilizare pelviană SAM II oferă un design simplu dintr-o singură bucată, cu niciun hardware detașabil. Este compactă, ușor de utilizat (în doar 3 pași) și ușor de montat (de obicei în mai puțin de un minut.) Mărimea se potrivește, fără a fi nevoie de ajustări suplimentare, pentru aproximativ 98% din populația adultă.
Centura nu are nevoie de expertiza unei persoane specializate pentru a fi montată și oferă un feedback ușor de recunoscut – prin sunet și duritate la atingere – atunci când este aplicată în mod corect. Catarama este programată să oprească manevra de tragere a curelei de îndată ce forța de compresie corectă a fost atinsă (doi dinți metalici sunt eliberați din cataramă pentru a opri cureaua din a se mai strânge în jurul pacientului).
Centura este foarte rezistentă și nu poate fi afectată de temperaturi extreme sau umiditate, dar nici de expunerea la obiecte sau suprafețe tari și/sau ascuțite.
De asemenea, aceasta este invizibilă pentru razele X, poate fi folosită în condiții de siguranță în timpul oricărui fel de investigații medicale, și poate fi curățată pentru refolosire cu ajutorul oricărui tip de soluții antimicrobiene sau detergenți standard.

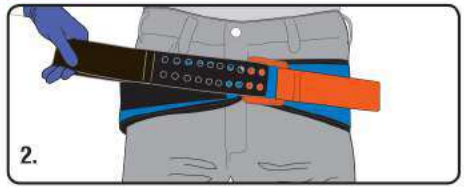
**Catarama conține două arcuri din oțel inoxidabil. Cercetătorii au declarat că "elementele s-au dovedit a fi neglijabile și nu au afectat vizualizarea fracturii posterioare". (Studiu clinic Krieg)*

Se aplică în doar 3 pași simpli

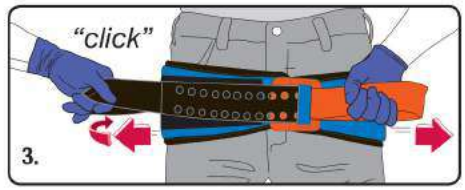
Fără ajustări, modificări, sau presupuneri



Se elimină obiectele din buzunarele pacientului și din zona pelviană. Centura se așează sub șoldurile pacientului, cu partea neagră în sus.



Cureaua neagră se trece prin cataramă și se trage până la capăt.



Se ține **cureaua portocalie** fixă, în timp ce **cureaua neagră** se trage în direcția opusă, până când simțiți și auziți „click”-ul cataramei. Se menține tensiunea corectă și se apasă imediat **cureaua neagră** pe suprafața Velcro a atelei, pentru a o asigura. Este posibil să auziți un al doilea „click” atunci când centura este corect aplicată.

Limitează Compresia pentru Aplicarea unei Forțe Eficiente

Centura pentru imobilizare pelviană SAM II este proiectată pentru a nu putea fi aplicată mai strâns sau mai lejer decât este nevoie, spre deosebire de restul echipamentelor medicale de același gen, care permit ca o forță nelimitată să poată fi aplicată asupra pacientului. Cercetătorii din sistemul legal al sănătății au condus numeroase studii clinice pentru a determina intervalul optim de forța ce poate fi exercitată în siguranță pentru închiderea corectă a unei fracturi pelviene instabile.

Catarama Autostop patentată, de care centura beneficiază, este programată să se oprească de fiecare dată exact atunci când forța de compresie corectă a fost obținută. Acesta este un element vital în medii de stres ridicat, unde o forța prea mare aplicată, de către personalul medical aflat sub presiune, se poate dovedi a fi periculoasă.

Chirurgii din întreaga lume recunosc importanța stabilizării facturilor pelviene în timpul primei ore de la incident – denumită și „ora de aur”. Din cauza posibil devastatoarelor efecte ale hemoragiei asociate unor astfel de fracturi, protocolul standard de prim ajutor include aplicarea unui tip de centuri de compresie, în jurul șoldurilor victimei.

Cod. produs	Descriere produse
SL556652-SM	Mărime S: Circumferință șold: 69-119cm
SL556652	Mărime Standard: Circumferință șold: 81-127cm
SL556652-LG	Mărime L: Circumferință șold: 91-152cm
SL556652-OD	Militar: Culoare Olive, Circumferință șold: 81-127cm

Studii de cercetare

In a Sling: An Integrated Review of Pelvic Binders as a Best Practice; Hall, Nicholas, Giodt, David; EMS1.com; 2013 Feb. 5.

Car Versus Bicycle: Conclusion; David W. Ross, DO, FACEP, Carol Wichman, BSN, MSN, and Mike MacKinnon, BSN, CEN, CCRN, CCFRN; Air Medical Journal; 28:6, 268-271, 2009.

New Concepts in the Prehospital and ED Management of Pelvic Fractures; Marvin A. Wayne, MD; Israeli Journal of Emergency Medicine; 6:1, 39-42, 2006.

Emergent Stabilization of Pelvic Ring Injuries by Controlled Circumferential Compression: A Clinical Trial; James C. Krieg, MD, Marcus Mohr, MS, Thomas J. Ellis, MD, Tamara S. Simpson, MD, Steven M. Madey, MD, and Michael Bottlang, PhD; Journal of Trauma; 59:659-664, 2005.

Noninvasive Reduction of Open-Book Pelvic Fractures by Circumferential Compression; Bottlang, M., Simpson, T., Sigg, J., Krieg, J.C., Madey, S.M., Long, W.B.; Journal of Orthopedic Trauma; 16:6, 367-73, 2002.

Emergent Management of Pelvic Ring Fractures with Use of Circumferential Compression; Bottlang, M., Krieg, J. C., Mohr, M., Simpson, T. S., Madey, S.M.; Journal of Bone and Joint Surgery; 84-A (Supplement 2): 43-47, 2002.

Made in USA

CE

Întrebări frecvente

De ce contează forța circumferențială aplicată, în tratamentul fracturilor pelviene?
La momentul evaluării inițiale, tipul exact de fractură este de cele mai mult ori încă necunoscut. În unele cazuri, o forță prea scăzută nu va reuși să închidă sau să stabilizeze factura; în alte situații, o forță prea mare poate duce la prăbușirea inelului pelvin.
Centura pentru imobilizare pelviană SAM II este singura centură de uz medical pre-programată să aplice doar forța corectă și sigură pentru toate tipurile de fracturi.

Care este diferența dintre Centura pentru imobilizare pelviană SAM II și alte echipamente de gen,utilizate în medicina de urgență?
Centura pentru imobilizare pelviană SAM II este proiectată de așa natură încât să nu poată fi strânsă mai tare decât este nevoie. Astfel, este singurul echipament de acest gen care nu va permite ca o forța mai mare decât cea necesară să fie aplicată asupra fracturii. Din acest motiv, asigură compresia corectă și sigură de fiecare dată. Acest aspect este documentat în aproape 100 de articole de specialitate și prezentări în plen, atât naționale cât și internaționale.

Centura pentru imobilizare pelviană SAM II poate fi utilizată și în cazul suspectării de factură pelviană, chiar dacă nu a fost identificată o fractură deschisă?
Nu au fost raportate contraindicații cu privire la utilizarea atelei, indiferent de natura fracturii.

Cum afectează Centura pentru imobilizare pelviană SAM II suprafața pielii?
Valoarea presiunii exercitate la suprafață a fost măsurată, iar aceasta s-a dovedit a fi de regulă extrem de scăzută. În cazul în care atela este aplicată pentru perioade îndelungate, pielea ar trebui să fie inspectată la intervale regulate. În aceste cazuri, atela ar trebui îndepărtată periodic pentru a putea reacomoda volumul pelvian. Aveți grijă la faptul că centura ar trebui să fie eliberată foarte încet!

Cum se curăță Centura pentru imobilizare pelviană SAM II?
Centura poate fi curățată prin spălare manuală, cu detergenți standard sau soluții antimicrobiene cu spectru larg de acțiune. Aceasta poate fi reutilizată ori de câte ori este nevoie.

Distribuitorul dumneavoastră:

DESPRE PRODUSELE SAM MEDICAL:

SAM® Medical Products este determinat să aducă soluții inovatoare de piață, care să răspundă nevoilor medicinii de urgență, ale armatei și spitalelor din întreaga lume. SAM® Splint este standardul de aur al atelelor flexibile. Ne mândrim astfel cu crearea de produse de calitate care ridică ștacheta industriei. Toate gamele noastre de produse se concentreaza in principal pe managementul fracturii și îngrijirea rănilor, și includ SAM® atelă, SAM® atelă pelviană II, SAM® atelă moale, SAM® garou pentru încheieturi și multe altele. Având sediul central in Wilsonville, Oregon, produsele noastre sunt distribuite la nivel global în peste 60 de țări. Aflați mai multe la: www.sammedical.com.

SAM MEDICAL PRODUCTS®

sammedical.com | customerservice@sammedical.com | 800.818.4726
P.O. Box 3270 Tualatin, OR 97062 | 503.639.5474 | Fax 503.639.5425

SLI-206-CIV-6

Subsemnata **ZAHARIE CRISTINA VICTORIA**, traducător autorizat de M. J. cu nr. **17502/2006**,

certific exactitatea traducerii cu textul înscrisului în copie în limba engleză.

TRADUCĂTOR **ZAHARIE CRISTINA VICTORIA** - *AUTORIZAT* cu nr. **17502/2006**

Traducător și Interpret Autorizat
ZAHARIE CRISTINA VICTORIA
Aut. M.J. nr. 17502
Engleză

EU DECLARATION OF CONFORMITY AS PER ANNEX IV OF THE REGULATION (EU) MDR 2017/745

Manufacturer:	**SAM® Medical Products** 12200 SW Tualatin Road, Suite 200, Tualatin, OR 97062, USA Tel: + 1 (503) 639-5474 | Fax: +1 (503) 639-5425 quality@sammedical.com Single Registration Number (SRN): US-MF-000002589
EU Authorized Representative:	**Emergo Europe** Prinsessegracht 20, 2514 AP The Hague, The Netherlands Tel: +31 (0)70 345 8570 emergoeurope@ul.com Single Registration Number (SRN): NL-AR-000000116
Product Family Name	SAM® Pelvic Sling II
Basic UDI-DI:	0822045SL01U6 (see details in Table 1 attached)
Device(s) concerned:	This Declaration applies to all devices and variants included within the *SAM® Pelvic Sling II Product Family* (see details in Table 1 attached).
Intended Purpose	The SAM Pelvic Sling II is a non-invasive, circumferential pelvic belt intended to stabilize pelvic fractures during transport to a definitive care facility.
Risk Class per Annex VIII:	Class I (non-sterile) as per Rule 1
GMDN Code	63496 (Pelvic binder, single use)
EMDN Code	M0305099 (Immobilization Systems and devices – Other)
Notified Body:	Not applicable. Class I (non-sterile, non-measuring, non-reusable) devices are not reviewed by a Notified body.
Conformity Assessment Route:	SAM Medical® Products utilizes Annex II and Annex III Technical Documentation (including PMS) for Class I EU medical devices and issues a Declaration of Conformity (self-certification).
Applicable CE Certificate(s):	Not applicable – Class I (non-sterile) devices are self-certified.
Standards and Common Specifications (CS):	This certificate further declares that the products covered herein also comply with the applicable requirements of relevant standards and Common Specifications specified in Table 2.

This declaration of conformity is issued under the sole responsibility of SAM® Medical Products. We hereby declare that the medical devices specified above meet the applicable provisions of the Medical Devices Regulation (EU) MDR 2017/745.

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

Person authorized to sign on behalf of SAM® Medical Products:

Signature & date: 2021-06-23

Name: Jeff Lipps
Position: Director RA/QA, SAM® Medical Products
Place of Issue: 12200 SW Tualatin Road, Suite 200, Tualatin, OR 97062, USA

Table 1: Medical devices and variants included in the *SAM® Pelvic Sling II Product Family*

Basic UDI-DI	GTIN	Product	Packaging Level	SKU
0822045SL01U6	00822045428621	SAM Pelvic Sling II Small 27 in-45 in (69 cm-114 cm)	Each	PS300-OB-EN
	10822045428628		Case	
	00822045428638	SAM Pelvic Sling II Standard 32 in-50 in. (81 cm-127 cm)	Each	PS301-OB-EN
	10822045428635		Case	
	00822045428614	SAM Pelvic Sling II Standard 32 in-50 in. (81 cm-127 cm) – Olive Drab	Each	PS301-OD-EN
	10822045428611		Case	
	00822045428645	SAM Pelvic Sling II Large 36 in-54 in (91 cm-137 cm)	Each	PS302-OB-EN
	10822045428642		Case	

Table 2: Standards and Common Specifications (CS) applied

Standard #	Title	Year / Version
Applied Standards		
EN 1041	Information supplied by the manufacturer of medical devices	2008+A1:2013
EN ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	2020
EN ISO 10993-18	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	2020
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016+AC:2018
EN ISO 14971	Medical Devices - Application of Risk Management to Medical Devices	2019
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
EN ISO 16061	Instrumentation for use in association with non-active surgical implants - General requirements	2015 See Footnote[1]
EN 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2015+A1:2020
Other relevant standards		
EN ISO 17100	Translation services — Requirements for translation services	2015+A1:2017
ASTM F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	2015
ASTM F2503-20	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	2020
Common Specifications		
-	No common specifications relevant to the device family have been published in OJ at this time.	

[1]Annex A was utilized for biocompatibility considerations.

EUDOC-0002 SAM Pelvic Sling II DoC (Exp. 2024-06-23)

Final Audit Report 2021-06-23

Created:	2021-06-23
By:	Dan Kim (Dan.Kim@sammedical.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA4KAjvhju1cKcw7_mbjHX0GYuIzUayD83

"EUDOC-0002 SAM Pelvic Sling II DoC (Exp. 2024-06-23)" History

Document created by Dan Kim (Dan.Kim@sammedical.com)
2021-06-23 - 8:24:31 PM GMT- IP address: 50.53.248.154

Document emailed to Jeff Lipps (jeff.lipps@sammedical.com) for signature
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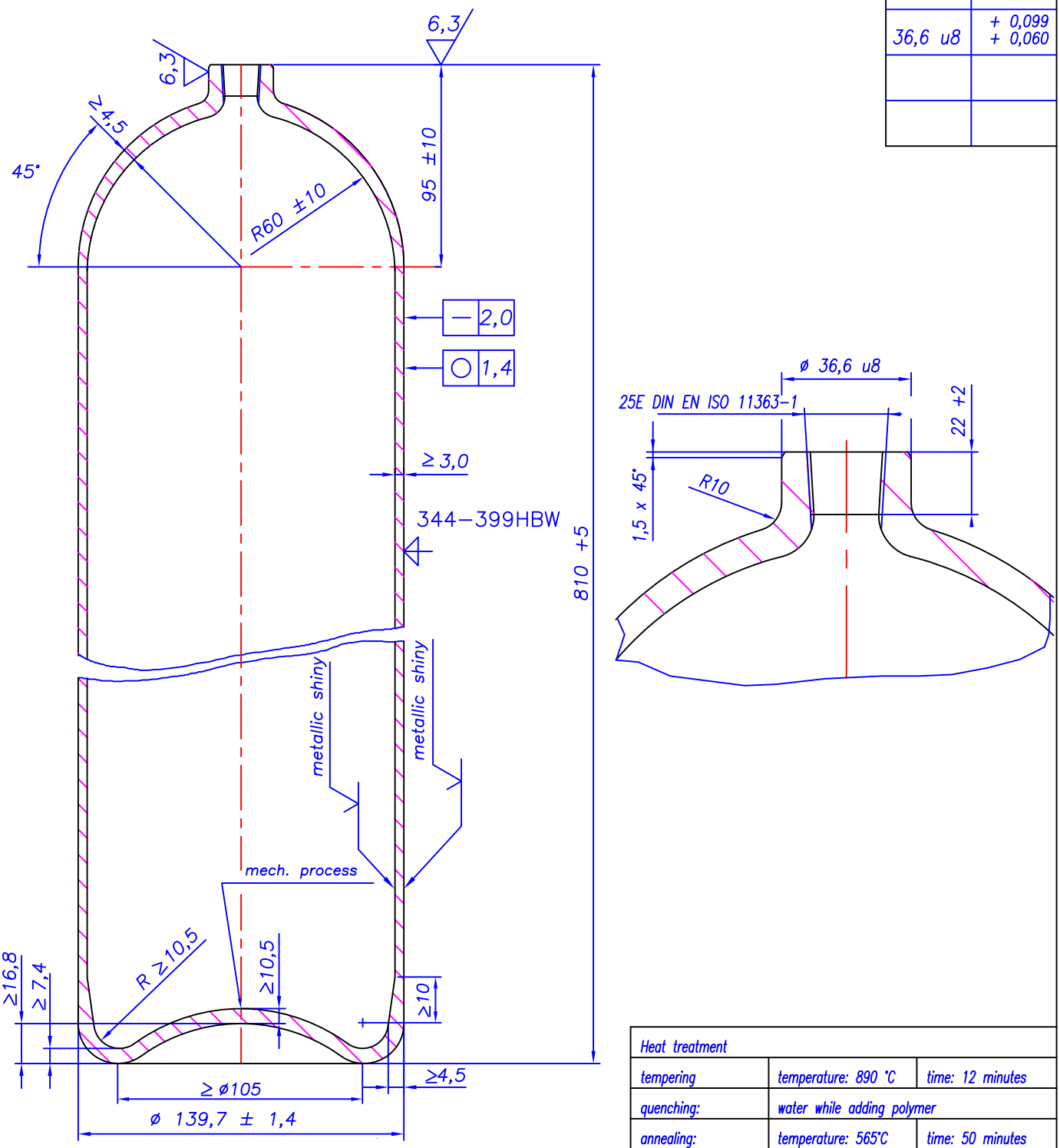
Document e-signed by Jeff Lipps (jeff.lipps@sammedical.com)
Signature Date: 2021-06-23 - 9:05:29 PM GMT - Time Source: server- IP address: 50.53.248.154

Agreement completed.
2021-06-23 - 9:05:29 PM GMT



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**

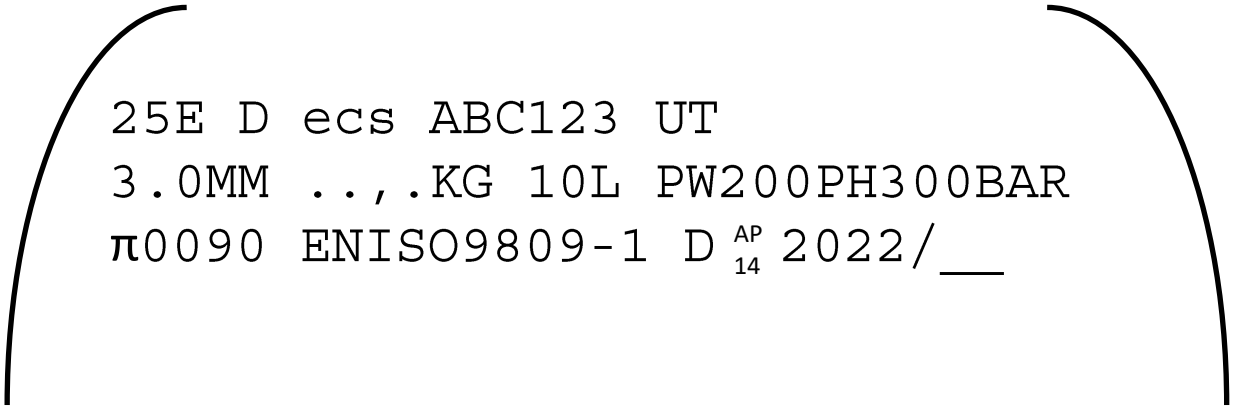
(test pressure) 300 bar

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

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

ecs AG
eurocylinder systems

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.

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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 / 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

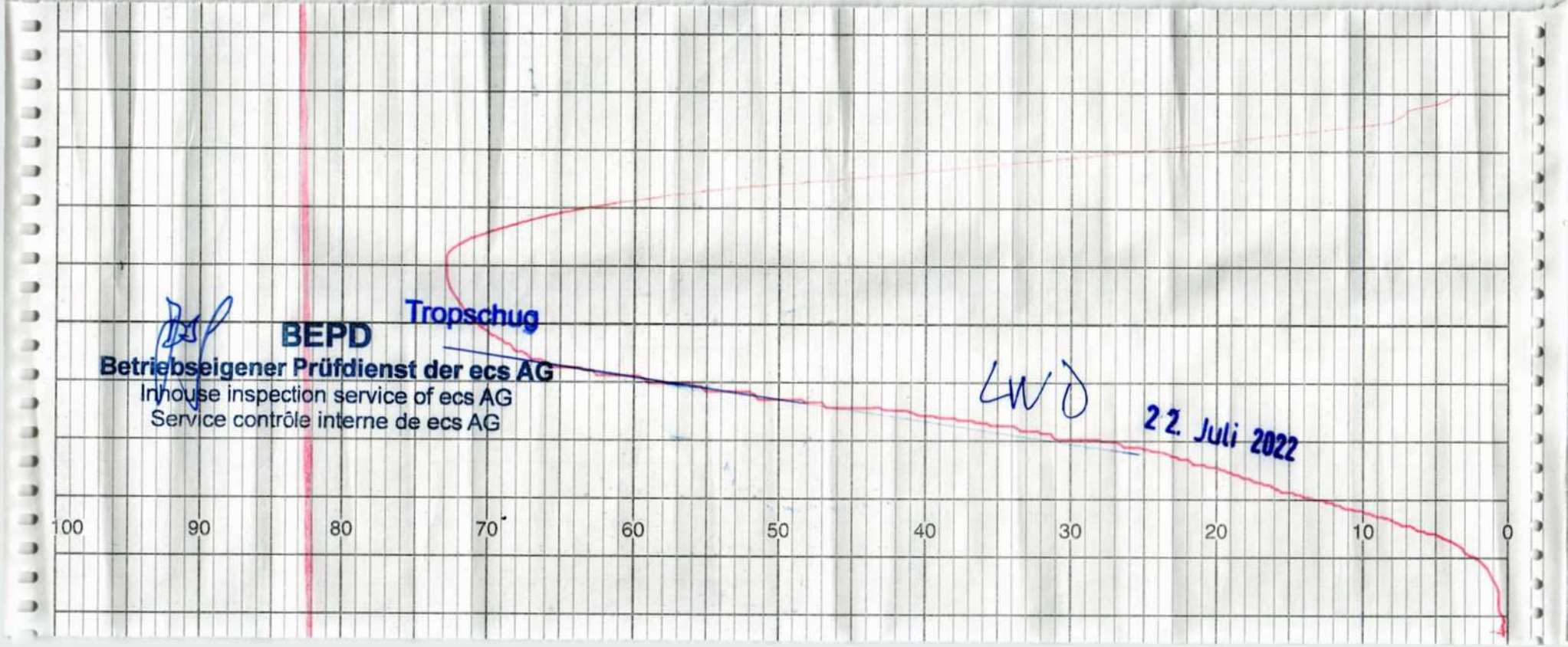
2. Bestätigung über die Einhaltung der technologischen Parameter
Compliance with technical parameters
Conformité des caractéristique techniques

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
Unterschrift signing signature / Datum date date


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

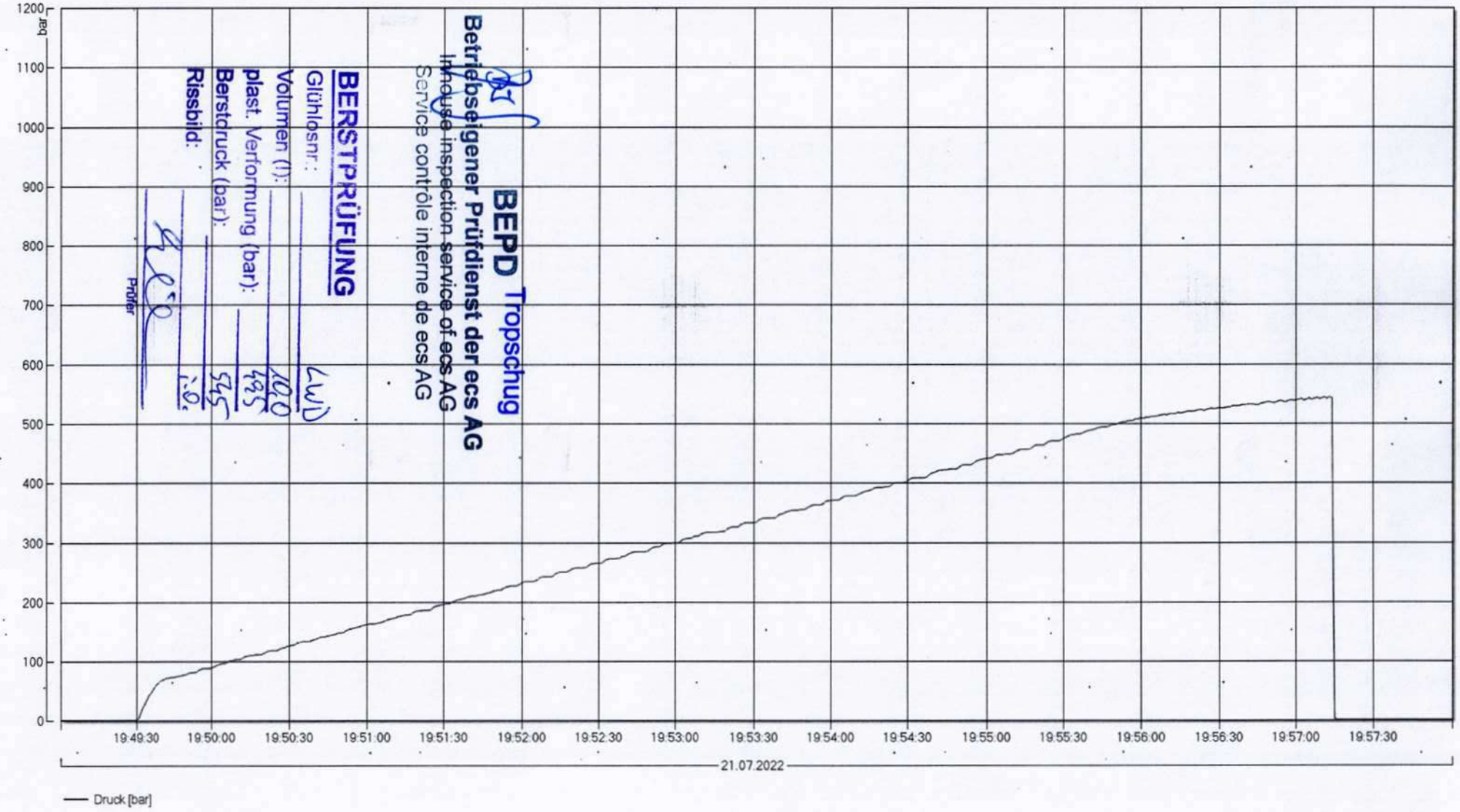
Leitung BEPD
direction inhouse inspection service/service de contrôle interne
Unterschrift signing signature/ Datum date date

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

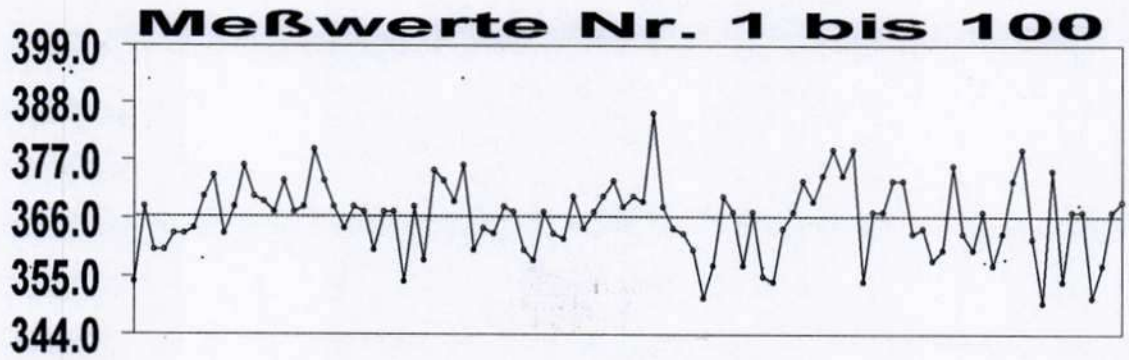
Statistikwerte :[HB 30]

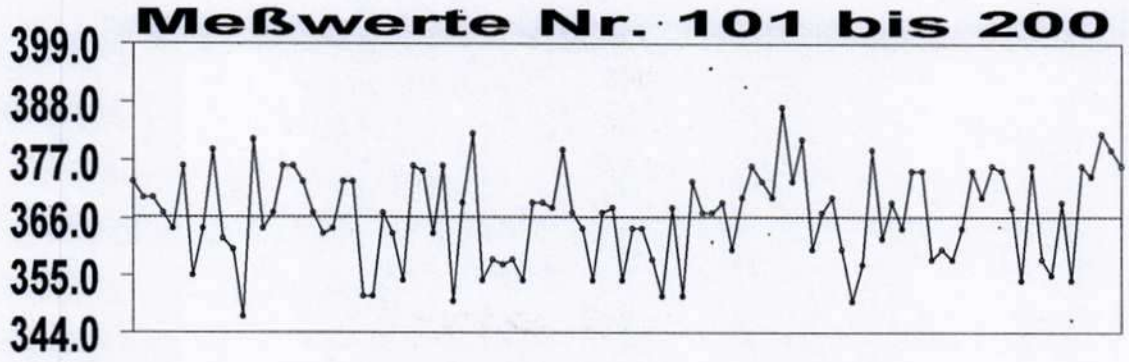
Gesamtanzahl	:	200
Anzahl in Grenzen	:	200
Anzahl zu weich	:	0
Anzahl zu hart	:	0
Anzahl ST	:	200
kleinster Wert	:	347.0
größter Wert	:	387.0
Xquer	:	366.240
Standardabweichung		7.991

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

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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

APOLDA, 21.07.2022

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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

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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

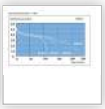
DATE TEHNICE

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

DNV·GL

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

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**

Certificate No.:
10401-2017-CE-CZS-NA-PS Rev. 5.0

Project No.:
PRJC-189266-2009-PRC-CZE

Valid Until:
27 May 2024

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

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.

MEDIMETER

Medimeter is a flowmeter intended for control and measurement of flow of air or oxygen administered to patients

MediMeter®
Flowmeter

EDITION 1/2011

ADVANTAGES

- Flat surface float allows easy and safe reading of flow values by the users
- Ergonomic desing, easy for cleaning
- Available with probe connector, rail mounting with a hose and twin versions
- Soft closing mechanism
- Resistant float against impact
- New scale - better reading of flow values

Technical Data

Gas pressure	O_2, air
Flow ranges	0 - 5 lpm
	0 - 15 lpm
	0 - 30 lpm
Inlet connection	according to national standard
Outlet connection	9/16" UNF, M12×1,25, G3/8,
	G 1/4 with hose nipple
Body material	Nickel-plated brass
O-rings	EPDM
Control knob	Polyamide
Body dimensions	Width 32 mm
	Height 160 mm
	Depth 60 mm
	Weight 280 g (without connector)
Temperature range:	
Storage	- 30 °C to + 60 °C
Operation	- 20 °C to + 60 °C
Regulatory status:	Complies with medical devices
	directive 93/42/EEC
	Complies with EN 15 002
	(Flow - matering devices for
	connection to terminal units of
	medical gas pipeline systems)
Classification:	Class IIa
Manufacturer:	GCE, s.r.o, Žižkova 381
	583 81 Chotěboř, CZ
CE - marking	CE0434

Accessories - HUMIDIFIERES

Art. Nr.	Description
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 world-wide: http://www.gcegroup.com

Art. Nr. 73510000525. Edition 1/2011. 07022011md © 2011

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**

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

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

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.

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**

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

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 042208 0032 Rev. 00

Manufacturer:
OSCAR BOSCAROL S.R.L.
Via Enzo Ferrari, 29
39100 Bolzano (BZ)
ITALY

Facility(ies):
OSCAR BOSCAROL S.R.L.
Via Enzo Ferrari, 29, 39100 Bolzano (BZ), ITALY

Product Category(ies): **Pressure regulators for medical gases, compressed medical gases pipeline set for road ambulances and emergency vehicles, medical suction equipments, defibrillators**

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. See also notes overleaf.

Report No.: ITA1311593

Valid from: 2019-07-23
Valid until: 2023-03-01

Date, 2019-07-23

Stefan Preiß
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

TÜV®

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Oscar Boscarol S.r.l.

Via Enzo Ferrari, 29

IT - 39100 Bolzano (BZ)

BOSCAROL®
Emergency Medical Systems

has established and applies a quality management system
for the following scope:

Design, manufacturing, servicing and placing on the market of medical aspirators and related accessories, kits for the administration of compressed medical gases for ambulances and emergency vehicles, bags and medical devices for immobilization and rescue.
Trade and servicing of pressure reducers for use with medical gases.
Trade and servicing of defibrillators.
Trade of active devices for monitoring of physiological parameters.
Trade of sterile and non-sterile devices for medication.
Trade of devices for ventilation and resuscitation. EA 14, 17, 19, 29

Through an Audit, Report No. 7978453040DR20, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI EN ISO 9001:2015

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 00 1382112.**

This Certificate is valid from 2023-02-07 to 2024-09-14.

The reference date for all the next audits is (day-month): 15-06.

Milan, 2023-02-07. First Certification: 2007-12-19

The certification responsible: Elena Re
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

ACCREDIA
SGQ N° 083 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

TÜVRheinland CERTIFIED
Management System
ISO 9001:2015
www.tuv.com
ID 9000019567

www.tuvitalia.com

TÜVRheinland®

CERTIFICATO

L'Organismo di Certificazione TÜV Rheinland Italia S.r.l.

certifica, in accordo alle procedure TÜV Rheinland Group, che l'azienda

Oscar Boscarol S.r.l.

Via Enzo Ferrari, 29

IT - 39100 Bolzano (BZ)

BOSCAROL®
Emergency Medical Systems

ha istituito ed attua un sistema di gestione per la qualità
relativo al seguente campo di applicazione:

Progettazione, fabbricazione, assistenza tecnica e immissione in commercio di aspiratori per uso medico e relativi accessori, kit per la somministrazione di gas medicali compressi ad uso ambulanze e veicoli per l'emergenza, borse e dispositivi medici per l'immobilizzazione e il soccorso.
Commercializzazione e assistenza tecnica di riduttori di pressione per l'utilizzo con gas medicali.
Commercializzazione e assistenza tecnica di defibrillatori.
Commercializzazione di dispositivi attivi per il monitoraggio dei parametri fisiologici.
Commercializzazione di dispositivi sterili e non sterili per la medicazione.
Commercializzazione di dispositivi per la ventilazione e rianimazione. EA 14, 17, 19, 29

Mediante un audit, rapporto N° 7978453040DR20, è stata conseguita
dimostrazione che il sistema di gestione per la qualità è conforme alla Norma

UNI EN ISO 9001:2015

Fare riferimento al Manuale della Qualità per
i dettagli sulle esclusioni rispetto ai requisiti della norma.

N° di registrazione del certificato: **39 00 1382112**.

Il presente certificato è valido dal 07/02/2023 al 14/09/2024.

La data di riferimento per le verifiche di sorveglianza annuali è (giorno/mese): 15/06

Milano, li 07/02/2023. Prima Certificazione: 19/12/2007

Il responsabile della Certificazione: Elena Re
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

ACCREDIA
SGQ N° 083 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

TÜVRheinland® CERTIFIED
Management System ISO 9001:2015
www.tuv.com ID 9000019657

www.tuvitalia.com

TÜVRheinland®

Luxfer
Gas Cylinders

CYLINDER TYPE: 634/1/Q

TECHNICAL CHARACTERISTICS

1.1 Dimensions:

Water Capacity (min.)-	2.0	litres
Minimum Wall Thickness-	6.80	mm
Diameter (external)-	102	mm
Test Pressure -	300	bar
Length (approx.)-	395	mm
Weight (Approx. Empty) -	2.54	kg

1.2 Minimum Mechanical Properties:

0.2% Proof	280 N/mm^2
UTS	330 N/mm^2
Elongation	12%

1.3 Material:

Aluminium alloy AA6061 is an alloy containing magnesium and silicon in proportion to form magnesium silicide, thus making the alloy heat treatable. The alloy combines medium strength, good formability and machinability with excellent corrosion resistance.

1.4 Composition:

	WT/%		
	Min		**Max**
Silicon	0.40	-	0.8
Iron			0.7
Copper	0.15	-	0.40
Manganese			0.15
Magnesium	0.8	-	1.2
Chromium	0.04	-	0.35
Zinc			0.25
Titanium			0.15
Lead			0.0030*
Bismuth			0.0030*
Others {Each			0.05
{Total			0.15

* Limit set by Luxfer on Suppliers

1.5 Properties (Typical):

Temper Condition	**0.2% Proof N/mm^2**	**UTS N/mm^2**	**Elongation % (On $5.65\sqrt{S_o}$)**
T6	315	356	14.2

1.6 Physical Constants:

Specific gravity	2.7
Electrical conductivity	43.1% IACS
Modulus of elasticity	69 Gpa

1.7 Manufacturing Process:

Luxfer manufacture seamless aluminium alloy cylinders by cold impact extrusion. The open end of the shell formed by extrusion is subsequently closed by heading (hot formed in a die) to give the characteristic cylinder profile. Solution heat treatment, quenching into cold water and artificial ageing is carried out to develop the mechanical properties. This is followed by machining of the threads, stamping of marks and inscriptions, pressure testing, internal cleaning, full inspection, painting as required and packing.

SECTION TWO STRENGTH CALCULATIONS

2.1 Calculation of Minimum Wall Thickness:

Based on wall thickness equation from the EC Directive 84/526/EC :

Cylinder Type: 634/1/Q

Use,
$$a = \frac{P_h \cdot D}{\frac{20 \cdot R}{4/3} + P_h}$$

Where,

a	=	Minimum Wall Thickness - (mm)
P_h	=	Hydraulic Test Pressure - (bar)
D	=	Nominal External Diameter of Cylinder - (mm)
R	=	Lesser of R_e or 0.85 R_m
R_e	=	0.2% proof stress of material - (N/mm^2)
R_m	=	Tensile strength of material - (N/mm^2)

For 634/1/Q

P_h	=	300	bar
D	=	102	mm
R_e	=	280	N/mm^2
R_m	=	330	N/mm^2
R	=	Lesser of 280 or 0.85 x 330 = 280.5	N/mm^2

$$a = \frac{300 \cdot 102}{\frac{20 \cdot 280}{4/3} + 300}$$

$\therefore$ a = 6.80 mm

This is the value of 6.80 mm shown on the cylinder drawing.

The minimum wall thickness of 6.80 mm is greater than $\left(\frac{D}{100}+1.5\text{mm}\right)$

Where D = External diameter.

i.e. min. wall of 634/1/Q is 6.80 mm $\left(\frac{D}{100}+1.5=2.52\text{ mm}\right)$

2.2 Hydraulic Burst Test

Cylinder Type: 634/1/Q

The measured burst pressure (P_r) shall be not less than:

$$P_{rt}=\frac{20a\cdot R_m}{D-a}$$

Where; P_r = Actual burst pressure measured during testing - bar
P_{rt} = Calculated minimum theoretical burst pressure - bar
a = Calculated minimum wall thickness - mm
D = The nominal external diameter of the cylinder – mm
Rm = The minimum guaranteed tensile strength – N/mm^2

Applying to the 634/1/Q:

Where; a = 6.80 mm
D = 102 mm
Rm = 330 N/mm^2

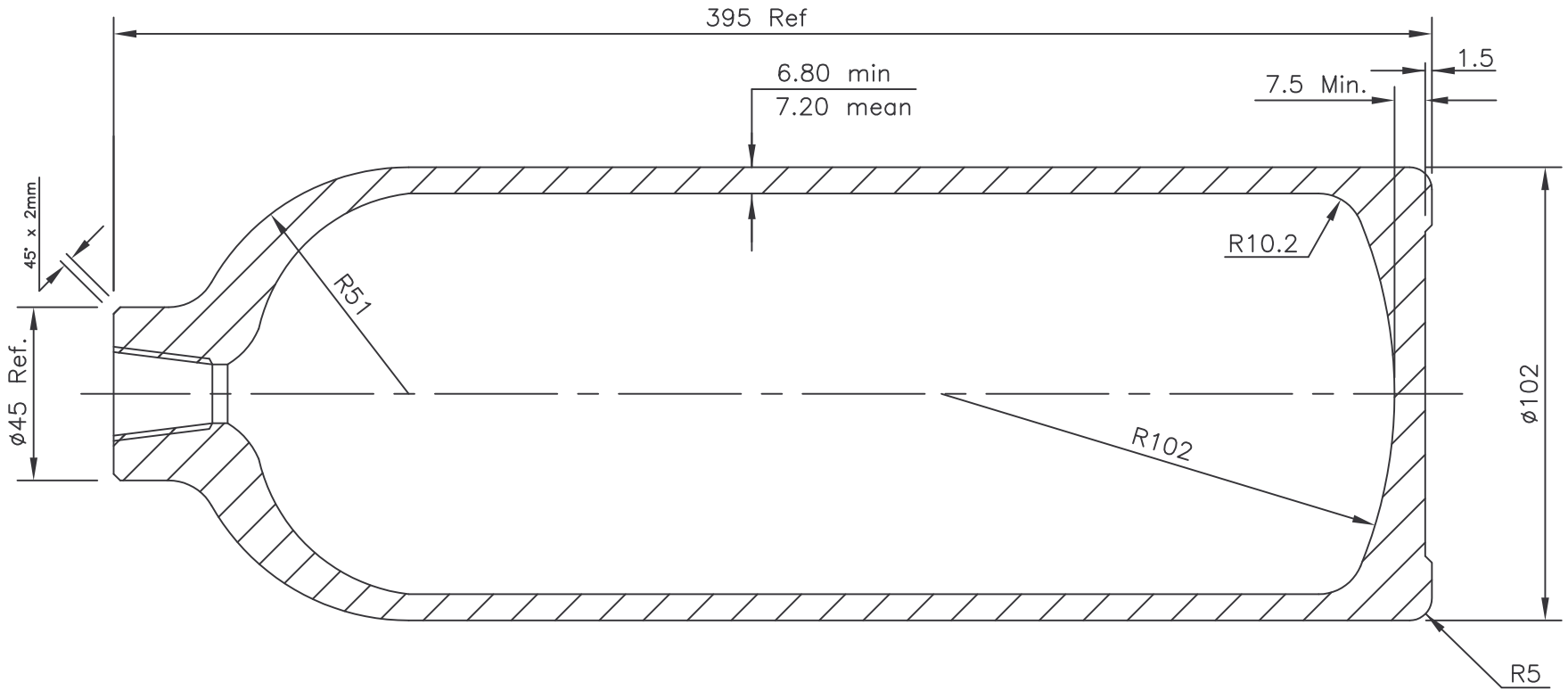
Then,

$$P_{rt}=\frac{20\cdot 6.80\cdot 330}{102-6.80}$$

∴ **P_{rt} = 472 bar**

Simon Nicholson
Senior Design Engineer

Luxfer Gas Cylinders Ltd.



MATERIAL: ALUMINIUM ALLOY AA 6061 T6	WATER CAPACITY: 2.00L (Min)	CHARGING PRESSURE @15°C: 200 BAR	CHECKED	A.S.N.	© LUXFER GAS CYLINDERS LTD. 2011 The copyright of this drawing belongs to Luxfer Small Cylinders. It is supplied on the express terms that it is to be treated as confidential and is not to be copied or communicated to any other person. It is not to be used for the purpose of construction or manufacture unless expressly authorised for that purpose on each occasion that it is used.
UTS (min.): 330 N/mm²	EMPTY WEIGHT: 2.54 Kg (Min.)	DEVELOPED PRESSURE ———	DATE	18.May.11	
0.2% PROOF STRESS: 280 N/mm²	THREAD: 28.8 DIN477	TEST PRESSURE: 300 BAR	DESIGN: E.E.C.	ALL DIMENSIONS IN MM U.O.S. GENERAL TOLERANCE ±0.5	TITLE: 2.0L PERMANENT GAS CYLINDER
ELONGATION ON: 5.65 √A (min.) 12%	FILLING RATIO: ———	BURST PRESSURE: (min.) ———			L.S.C. No.: 634/1/Q ISSUE : 2 Taken From 423/1/Q Family Drawing M5409

LUXFER
GAS CYLINDERS

Colwick, Nottingham, NG4 2BH, England
Tel: [44] (0115) 980 3800
Fax: [44] (0115) 980 3899
www.luxfercylinders.com

European Authorized Representative
OBELIS S.A. Bd Général Wahis 53, B-1030 Brussels, BELGIUM
Phone: +32 (0)2 732 594, Fax: +32 (0)2 732 6003
Email: mail@obelis.net
Representative: Mr. Gideon Elkayam

Certificate No. TPED0014328 **Issue No.**

Directives 2010/35/EU (TPED), 2008/68/EC

Declaration of Conformity

Customer Name REV GAS INDUSTRIES LTD

Address
KOBANYAI UT 49
BUDAPEST 1101
HUNGARY

Customer Order Reference BGZ23-00039-1

Sales Order / Works Order Number 508615/100270588

Manufacturer Luxfer Gas Cylinders Ltd. Colwick, Nottingham NG4 2BH. UK

Description of Pressure Equipment

Seamless aluminium alloy AA6061 high pressure gas cylinders

Conformity Assessment Procedure Followed: ADR 6.2.2.11: Xa IS

Design Specification: 84/526/EEC

EC Type Examination Certificate Reference No: 01/GB/230

Cylinder Type: A634/1/Q **Manufacture Date** 03/2023

Cylinder Capacity 2.0lt.

TPED Details of Valves (if fitted - if not fitted must state "Valves Not Fitted"):

Valves Not Fitted

Notified Body monitoring Luxfer's Quality Assurance System under the TPED for IS:

LRQA Nederland B.V. (0343), George Hintzenweg 77, 3068 AX Rotterdam, The Netherlands.

Cylinder Serial Numbers covered by this Declaration of Conformity:

Serial No. - M053826 - M054125

Total Number of Cylinders 300

Declaration The above noted cylinders are in compliance with the requirements of Directive 2010/35/EU and conform to the regulation(s)and standard(s) mentioned in the EC Type examination (Module B) or in the type approval (1.8.7.2 from the ADR 2021) and with the pertinent requirements of 6.2 of ADR 2021. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed

Simon Nicholson, Senior Design Engineer for & on behalf of Luxfer Gas Cylinders Ltd.

Luxfer's Official Stamp QUALITY RELIABILITY

Initials of Issuer Sign: T Cameron

Issue Date 10/03/2023

LUXFER
GAS CYLINDERS

Colwick, Nottingham, NG4 2BH, England.
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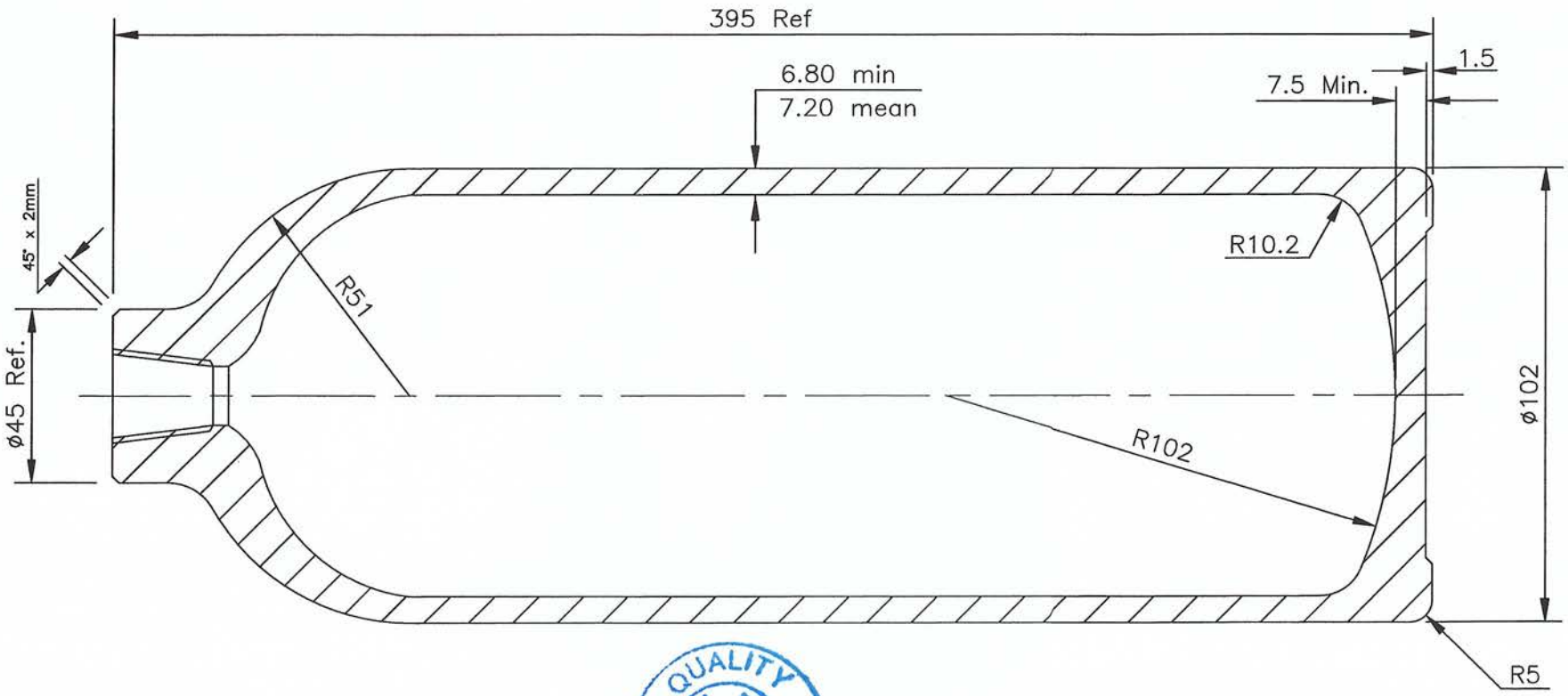


MATERIAL: ALUMINIUM ALLOY AA 6061 T6	WATER CAPACITY: 2.00L (min.)	CHARGING PRESSURE @15°C: 200 BAR	DRAWN A.S.N.	DATE 22.July.2020	© LUXFER GAS CYLINDERS LTD.2020
UTS (min.): 330 N/mm^2	EMPTY WEIGHT: 2.54 Kg (approx.)	DEVELOPED PRESSURE ——	CHECKED P.H.	DATE 22.July.2020	The copyright of this drawing belongs to Luxfer Gas Cylinders. It is supplied on the express terms that it is to be treated as confidential and is not to be copied or communicated to any other person. It is not to be used for the purpose of construction or manufacture unless expressly authorised for that purpose on each occasion that it is used.
0.2% PROOF STRESS: 280 N/mm^2	THREAD: 25E	TEST PRESSURE: 300 BAR	DESIGN: The design and manufacture of this cylinder conform to: 84/526/EEC 2010/35/EU (TPED)		
ELONGATION ON: 5.65 $\sqrt{A}$ (min.) 12%	FILLING RATIO: ——	BURST PRESSURE: (min.) 472 BAR	Based on Approved Type: 423/1/Q EC Approval No.: 84/526/EEC/UK18 TPED Approval Certificate: 01/GB/230		All Dim. in mm u.o.s.

TITLE 2.0L Permanent Gas Cylinder

634/1/Q ISSUE : 3 M6378

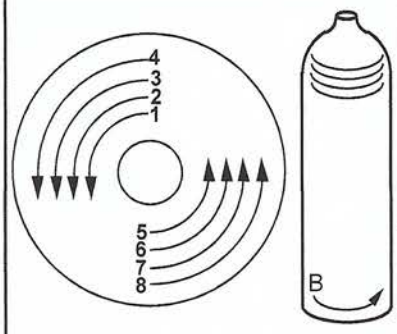
A102Z75

LUXFER
GAS CYLINDERS

CUSTOMER MARKING INSTRUCTION SHEET

Cylinder Type	634/1/Q			Suffix: 33		Issue No: 2	
Customer	REV GAS INDUSTRIES LTD.					Mod. No: M6668	
Approved For:	TPED (2010/35/EU)						
Drawn	A.S.N.	Date	06.05.22				

Stamping Positions :



For Internal use only

Cyl. Diameter :	102mm
Nose ref:	--------
Packing Req:	--------

VALVE WEIGHT	------- KG
CAGE WEIGHT	------- KG
COLLAR WEIGHT	------- KG
CIRCLIP WEIGHT	------- KG
GAS WEIGHT	------- KG

Line	Char Size	Description
1		
2	3 mm	25E GB LUXFER 634 - [1] AA6061 T6
3	3 mm	6.8MM [2] KG 2.0 L PW200 PH300BAR
4	3 mm	[3] 84/526 [4] (5) [6]
5		
6		
7		
8		
Base	3 mm	LUK [7] 102Z75 [8] [9]

Notes:

1) LUXFER SERIAL NUMBER
2) EMPTY WEIGHT OF CYLINDER ONLY
3) IDENTIFICATION NUMBER OF TPED NOTIFIED BODY (e.g. LRQA Netherlands B.V. = 0343)
4) COUNTRY OF APPROVAL OF INSPECTION BODY IN 3. (e.g. LRQA Netherlands B.V. = NL)
5) NOTIFIED BODY INSPECTION STAMP (e.g. LRQA)
6) YEAR FOLLOWED BY MONTH OF INITIAL TEST (e.g: 2022/05)
7) BATCH NUMBER
8) CAST NUMBER
9) INSPECTORS MARK FOR PROOF OF CONCENTRICITY VERIFICATION

QUALITY ★ RELIABILITY ★

LUXFER
GAS CYLINDERS

Colwick, Nottingham, NG4 2BH, England
Tel: +44 (0) 115 980 3800 Fax: +44 (0) 115 980 3899
www.luxfercylinders.com

Statement of Hydrostatic Pressure Test.

Customer: Rev Gas Industires, Kobanyai ut 49, Budapest 1101, Hungary.

Customer Order Reference: BGZ23-00039-1

Cylinders, Type **A634/1/Q** with the following Luxfer cylinder serial Nos. M053826 – M054125 as detailed on TPED Declaration of Conformity No. **TPED0014328** dated 10/03/2023, were all individually subjected to a successful Hydrostatic Pressure Test at a pressure of 300 bar held for a minimum of 60 seconds on the date stamped on the cylinders:

For & on Behalf of Luxfer Gas Cylinders Ltd:

QUALITY ★ RELIABILITY ★

P.S. Cameron

Certification Officer.
23/03/2023

LUXFER
GAS CYLINDERS

Colwick, Nottingham, NG4 2BH, England
Tel: +44 (0) 115 980 3800 Fax: +44 (0) 115 980 3899
www.luxfercylinders.com

Customer Requested Manufacturing Information.

General Information:

Customer: REV GAS INDUSTRIES LTD, KOBANYAI UT 49, BUDAPEST 1101, HUNGARY
Cylinder Type A634/11/Q
Luxfer Cylinder Serial Numbers: **M053826 – M054125**
Original TPED Declaration of Conformity No. **TPED0014328**
Customer Order Number: **BGZ23-00039-1**

Manufacturing Information:
Hydro Test Pressure: 300 Bar for 60 seconds minimum duration.
Material Cast Code:
KID (see attached material certificates).

Batch Mechanical Test Results:
UTS: Specification minimum value = 330 MPa
0.2% Proof Stress (Yield): Specification minimum value = 280 MPa
Elongation: Specification minimum value = 12%
Burst Pressure: Specification minimum value = 472 Bar

Cylinder Type	Batch (Cast)	Serial Nos.	Yield *(MPa)	UTS *(MPa)	Burst Pressure* (Bar)	% Elong*	Hydro Test Date
A634/11/Q	7230381 (KID)	M053286 – M053956	322.1	359.7	557	16.9	MARCH 2023
A634/11/Q	7230382 (KID)	M053957 – M054082	322.4	362.1	562	16.8	MARCH 2023
A634/11/Q	7230383 (KID)	M054083 – M054125	328.9	363.4	569	15.3	MARCH 2023

*Note: 1 tensile, bend and burst test per 202 cylinders per type, per material cast and heat treatment cycle.

Manufacturers Declaration:

Luxfer Gas Cylinders Ltd in Nottingham UK, Designed & Manufactured the Gas Cylinders stated above.

The above stated information is authentic & was extracted from the Manufacturing Records for the Cylinder Serial Numbers quoted. All tests results, in process inspections & measurement were fully in accordance with the Design Specification, the Approved Design Drawing & the Transportable Pressure Equipment Directive (TPED) 2010/35/EU as was previously declared on the TPED Declaration of Conformity that was issued when the Cylinders were first delivered.

For & on Behalf of Luxfer Gas Cylinders:

QUALITY RELIABILITY

Paul Cameron
Certification Officer
23/03/2023

Type : 634/1/Q
Drawing Issue : 3
Test Witness : TPED-D

Order No. : 100270588 / 100270587
Minimum Burst: 472
Spec : 84/526/EEC

Lot Number	Cast	Qty	Burst Batch	Burst Result	Tensile Batch	Width mm	Wall mm	Area mm²	Proof N/mm²	UTS N/mm²	Elong %	Bend
23/0816	KID	135	7230381	557	7230381	18.86	7.33	138.24	322.1	359.7	16.9	PASS
23/0817	KID	131	7230382	562	7230382	18.85	7.26	136.85	322.4	362.1	16.8	PASS
23/0818	KID	183	7230383	569	7230383	18.87	7.25	136.81	328.9	363.4	15.3	PASS

Samples tested in accordance with BS EN ISO 6892-1, 10.3.2 Testing rate based on strain rate (method A)

Signed for Luxfer Gas Cylinders

Dan Toporowski

QUALITY RELIABILITY

Signed for Inspection Authority

TYPE - A634-1-Q

GENERIC CODE - 102Z75

DATE - 7-3-23

INSPECTION - LRQA MOD D

QTY = 300/100

JOB ID No. 1250 1249

LUXFER ORDER No. 100270588 270587

CUSTOMER(S) - Rev Gas / MATAR EEC 155.3

		CAST	KID		KID		KID																
		LOT NUMBER	23/0816		23/0817		23/0818																
		BURST BATCH No.	7230381		7230382		7230383																
QA CHECKS ONLY	MIN WALL THICKNESS	6.8	7.16		7.20		7.12	/															
	MAX MID WALL THICKNESS		7.40		7.30		7.32																
	MIN BASE THICKNESS	7.5	8.11		8.14		8.07	/															
	WATER CAPACITY (L)	2.0L	2.05		2.05		2.05	/															
	EMPTY WEIGHT (Kg)	2.54 KG	2.55		2.56		2.55																
472	BURST RESULT (BAR)		557		562		569																
	Serial No (LBB TEST)																						
	TENSILE BATCH No.		7230381		7230382		7230383																
QA CHECKS ONLY	MIN WALL THICKNESS	6.8	7.06		7.11		7.12	/															
	MAX MID WALL THICKNESS		7.36		7.35		7.36																
	MIN BASE THICKNESS	7.5	8.10		8.13		8.08	/															
	WATER CAPACITY (L)	2.0L	2.05		2.05		2.05	/															
	EMPTY WEIGHT (Kg)	2.54 KG	2.56		2.56		2.55																
	COLLAR	N/A	BATCH	QTY	BATCH	QTY	BATCH	QTY	BATCH	QTY	BATCH	QTY	BATCH	QTY	BATCH	QTY	BATCH	QTY	BATCH	QTY	BATCH	QTY	BATCH
			7230381	135	7230382	131	7230383	183															

BATCH NUMBERS COVERED MAXIMUM 202 CYLINDERS

TOTAL QUANTITY			135		131		183																
Sign on lot completetion check all batches covered and are under the right cast, total the quantity in the lot			BS		MG		MG																
QA to sign box for correct information inputted into LOT																							

TOTAL= 449 0

155 3 EEC

APRAGAZ

Member of CEOC INTERNATIONAL

Chaussée de Vilvorde, 156
Vilvoordsesteenweg 156
B-1120 Bruxelles/Brussel
Tel.: 32 (0)2 264 03 60
Fax: 32 (0)2 268 89 58
http://www.apragaz.com
info@apragaz.com

BELAC
084 - INSP
17020

NOTIFIED BODY TYPE APPROVAL CERTIFICATE

Issued in accordance with Pt. 1.8.7.2.4 (Renewal) of ADR 2021 agreement and following:
Directive 2010/35/EU *(TPED)*
Directives 2008/68/EC *(Annex 1)* & 2020/1833/EU

Certificate N°:
01/GB/230
Index 1 – Rev. 1

Manufacturer: *LUXFER GAS Cylinders Ltd.*
Colwick, Nottingham, NG4 2BH
ENGLAND

Concerned Equipment: *Seamless aluminium alloy refillable Gas Cylinders.*

Drawing n° 834/1/Q Issue 4

Test pressure: ***300*** *bar*
Diameter (out): ***102*** *mm*
Wall thickness min (Cylindrical part): ***6.8*** *mm*
Bottom thickness min (Central part): ***7.5*** *mm*

Range of cylinders involved, according to Technical file "Cylinder Type: 423/1/Q"

	Min.	*Max.*
Cylinder Length (mm)	*306*	*823.5*
Water Capacity (L)	*1.5*	*4.7*

Concerned EC Directives & Standards used for this type approval (renewal):
TPED (2010/35/EU), ADR 2021 and Annex I, Parts 1 to 3 to 84/526/EEC

The conformity assessment of the concerned equipment will be performed in accordance with:

- Pt. 1.8.7.3 of ADR (Supervision of the manufacture)
- Pt. 1.8.7.4 of ADR (Initial inspection and tests)

This will be performed by a relevant body which can be either:

- A TPED - ADR notified / inspection body (**Xa**), *See Pt 6.2. of ADR, or*
- The in-house Inspection Service of the manufacturer (**IS**), *See Pt 6.2. of ADR.*

The manufacturer will be allowed to affix the ⅄ *mark followed by the appropriate notified body identification number to approved equipment under the conditions described in the chapter 3 of the TPED Directive (2010/35/EU).*

The Certificate is valid until 12th October 2031

Approval Date: ***25/02/2022***
Name: ***B. NEVE ir***
Position: ***General Manager***
Notified body identification n°: ***0029***
Signature:
Notified body (Xa): **APRAGAZ**
Notified body reference / Technical file: *0110/F.1390*

QUALITY RELIABILITY

Certificat d'analyse / Certificate of Analysis

SHA

Ref. client / CustomerRef. :
668350

Commande / Order
0010400668-10

Point d'origine / Point of Origin
SHAWINIGAN ALUMINIUM INC.
3201 , Avenue de l'Aluminium
Shawinigan
Québec, Canada
G9N 0E9

Expédié à / Ship to :
LUXFER GAS CYLINDERS LIMITED
COLWICK
NOTTINGHAM
NC, Great Britain
NG4 2BH

KID

Vendu à / Sold to :
LUXFER GAS CYLINDERS LIMITED
COLWICK
NOTTINGHAM
NC, Great Britain
NG4 2BH

Paul Cameron
18.07.2022

Date d'exp. / Shipping Date:	2021-11-08
Connaissement / Bill of Lading:	2626-133422-105902
Liste d'exp. / Shiplist:	105902
Équipement / Equipment :	7423A
Alliage (AA) / Alloy (AA) :	69271 (6061)
Produit / Product :	Aluminum Extrusion Ingot
Matériel Client / Customer Part:	
Dimension :	101 X 5500 MM 4.0 X 216.5 IN

Analyse en % du poids / Analysis in % of weight

No d'échantillon de coulée Sample No of Drop	No Lot Lot No	Poids net (kg) Net Weight (kg)	Poids net (lb) Net Weight (lb)	Pièces Pieces	Si Na	Fe Pb	Cu Sn	Mn	Mg	Cr	Zn	Ti	Bi	Ga
21110101B	8427564	1,204	2,654.366	10	0.60 0.0000	0.16 0.001	0.24 0.000	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
21110101B	8427565	1,203	2,652.161	10	0.60 0.0000	0.16 0.001	0.24 0.000	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
21110101B	8427566	1,202	2,649.956	10	0.60 0.0000	0.16 0.001	0.24 0.000	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
21110101B	8427567	1,203	2,652.161	10	0.60 0.0000	0.16 0.001	0.24 0.000	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
21110101B	8427568	1,204	2,654.366	10	0.60 0.0000	0.16 0.001	0.24 0.000	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
21110101B	8427569	1,205	2,656.570	10	0.60 0.0000	0.16 0.001	0.24 0.000	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
21110101A	8427570	1,203	2,652.161	5	0.59 0.0000	0.16 0.001	0.24 0.000	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓

Paquets : **Bundles :**	11	**Poids net :** **Net Weight :**	kg lb	13,237 29,183	**Pièces :** **Pieces :**	110	**Tare :**	kg lb	259 571	**Poids brut :** **Gross Weight :**	kg lb	13,496 29,754

LES LINGOTS TRI-LOK 23KG, LES LINGOTS EN FORME DE T, LES GUEUSES, LES LINGOTS DE LAMINAGE MIS AU REBUT ET AUTRES LINGOTS DE REFUSION ONT TENDANCE A FORMER DES CAVITÉS SUCEPTIBLES D'EMPRISONNER DE L'EAU, POUR ÉLIMINER L'HUMIDITÉ AVANT LEUR EMPLOI DANS TOUT PROCÉDÉ DE FUSION ET POUR PRÉVENIR LES RISQUES D'EXPLOSION, LES LINGOTS DEVRAIENT ETRE SOUMIS A UN SÉCHAGE INTENSIF PAR CHAUFFAGE PRÉLIMINAIRE AVANT DE LES INCORPORER À DU METAL EN FUSION. NE CONTIENT PAS DE MATIÈRE RADIOACTIVE. TRI-LOK 23 KG INGOT, TEE INGOT, SOWS, SCRAPPED SHEET INGOT ON OTHER INGOT FOR REMELTING ARE PRONE TO THE FORMATION OF SHRINKAGE CAVITIES WHICH WILL PERMIT ENTRAPMENT OF WATER. TO ELIMINATE MOISTURE PRIOR TO USE IN ANY MELTING OPERATION AND TO SAFEGUARD AGAINST POSSIBLE EXPLOSION HAZARDS. INGOTS SHOULD BE THOROUGHLY DRIED BY PREHEATING BEFORE LOADING THEM INTO MOLTEN METAL. DOES NOT CONTAIN RADIOACTIVE MATERIALS.

/ Ghita Ouaziz Paul Cameron
18.07.2022

L'EXACTITUDE DE CES ANALYSES EST DANS LES NORMES DES LIMITES COMMERCIALES.
THE ANALYSES HERE ARE ACCURATE WITHIN COMMERCIAL LIMITS.

Certificat d'analyse / Certificate of Analysis

SHA

Ref. client / CustomerRef. :
668350

Commande / Order
0010400668-10

Point d'origine / Point of Origin
SHAWINIGAN ALUMINIUM INC.
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Québec, Canada
G9N 0E9

Expédié à / Ship to :
LUXFER GAS CYLINDERS LIMITED
COLWICK
NOTTINGHAM
NC, Great Britain
NG4 2BH

Vendu à / Sold to :
LUXFER GAS CYLINDERS LIMITED
COLWICK
NOTTINGHAM
NC, Great Britain
NG4 2BH

Date d'exp. / Shipping Date: 2021-11-08
Connaissement / Bill of Lading: 2626-133422-105902
Liste d'exp. / Shiplist: 105902
Équipement / Equipment : 7423A

Alliage (AA) / Alloy (AA) : 69271 (6061)
Produit / Product : Aluminum Extrusion Ingot
Matériel Client / Customer Part:
Dimension : 101 X 5500 MM
4.0 X 216.5 IN

Analyse en % du poids / Analysis in % of weight

No d'échantillon de coulée / Sample No of Drop	No Lot / Lot No	Poids net (kg) / Net Weight (kg)	Poids net (lb) / Net Weight (lb)	Pièces / Pieces	Si	Fe	Cu	Mn	Mg	Cr	Zn	Ti	Bi	Ga
					Na	Pb	Sn							
21110101B				5	0.60	0.16	0.24	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
					0.0000	0.001	0.000							
21110101A	8427572	1,204	2,654.366	10	0.59	0.16	0.24	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
					0.0000	0.001	0.000							
21110101A	8427573	1,204	2,654.366	10	0.59	0.16	0.24	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
					0.0000	0.001	0.000							
21110101A	8427574	1,200	2,645.547	10	0.59	0.16	0.24	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
					0.0000	0.001	0.000							
21110101A	8427575	1,205	2,656.570	10	0.59	0.16	0.24	0.01	0.89	0.084	0.00	0.01	0.000	0.01 ✓
					0.0000	0.001	0.000							

Paquets :	11	**Poids net :**	kg	13,237	**Pièces :**	110	**Tare :**	kg	259	**Poids brut :** kg 13,496
Bundles :		**Net Weight :**	lb	29,183	**Pieces :**			lb	571	**Gross Weight :** lb 29,754

LES LINGOTS TRI-LOK 23KG, LES LINGOTS EN FORME DE T, LES GUEUSES, LES LINGOTS DE LAMINAGE MIS AU REBUT ET AUTRES LINGOTS DE REFUSION ONT TENDANCE A FORMER DES CAVITÉS SUCEPTIBLES D'EMPRISONNER DE L'EAU, POUR ÉLIMINER L'HUMIDITÉ AVANT LEUR EMPLOI DANS TOUT PROCÉDÉ DE FUSION ET POUR PRÉVENIR LES RISQUES D'EXPLOSION. LES LINGOTS DEVRAIENT ETRE SOUMIS À UN SÉCHAGE INTENSIF PAR CHAUFFAGE PRÉLIMINAIRE AVANT DE LES INCORPORER À DU METAL EN FUSION. NE CONTIENT PAS DE MATIÈRE RADIOACTIVE. TRI-LOK 23 KG INGOT, TEE INGOT, SOWS, SCRAPPED SHEET INGOT ON OTHER INGOT FOR REMELTING ARE PRONE TO THE FORMATION OF SHRINKAGE CAVITIES WHICH WILL PERMIT ENTRAPMENT OF WATER, TO ELIMINATE MOISTURE PRIOR TO USE IN ANY MELTING OPERATION AND TO SAFEGUARD AGAINST POSSIBLE EXPLOSION HAZARDS. INGOTS SHOULD BE THOROUGHLY DRIED BY PREHEATING BEFORE LOADING THEM INTO MOLTEN METAL. DOES NOT CONTAIN RADIOACTIVE MATERIALS.

/ Ghita Ouaziz
Paul Cameron
18.07.2022

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COLWICK
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NC, Great Britain
NG4 2BH

Vendu à / Sold to :
LUXFER GAS CYLINDERS LIMITED
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NOTTINGHAM
NC, Great Britain
NG4 2BH

Date d'exp. / Shipping Date: 2021-11-08
Connaissement / Bill of Lading: 2626-133422-105902
Liste d'exp. / Shiplist: 105902
Équipement / Equipment : 7423A

Alliage (AA) / Alloy (AA) : 69271 (6061)
Produit / Product : Aluminum Extrusion Ingot
Matériel Client / Customer Part:
Dimension : 101 X 5500 MM
4.0 X 216.5 IN

Analyse en % du poids / Analysis in % of weight					Si	Fe	Cu	Mn	Mg	Cr	Zn	Ti	Bi	Ga
No d'échantillon de coulée / Sample No of Drop	No Lot / Lot No	Poids net (kg) / Net Weight (kg)	Poids net (lb) / Net Weight (lb)	Pièces / Pieces	Na	Pb	Sn							

THIS IS TO CERTIFY THAT THE UT INSPECTION, EXCESS SILICON, GRAIN SIZE, HARDNESS AND HYDROGEN REQUIREMENTS HAVE ALL BEEN MET.
MATERIAL COMPLIES WITH SPECIFICATION WPS GLOBAL-6061-001, ISSUE 02
CERTIFICATE IS IN ACCORDANCE WITH THE BS EN 10204-2004(E): CERTIFICATE TYPE 3.1
NO MORE THAN 2 CAST (HEAT) NUMBERS SHOULD BE SHIPPED AT THE SAME TIME/LOAD
USE HARD WOOD ONLY FOR BRACING
H.S. CODE 7601.20
ALUMINIUM ALLOYED INGOT
THIS IS TO CERTIFY THAT THE UT INSPECTION, EXCESS SILICON, GRAIN SIZE, HARDNESS AND HYDROGEN REQUIREMENTS HAVE ALL BEEN MET.
MATERIAL COMPLIES WITH SPECIFICATION WPS GLOBAL-6061-001, ISSUE 02
CERTIFICATE IS IN ACCORDANCE WITH THE BS EN 10204-2004(E): CERTIFICATE TYPE 3.1

Paquets : / **Bundles :**	11	**Poids net :** / **Net Weight :**	kg / lb	13,237 / 29,183	**Pièces :** / **Pieces :**	110	**Tare :**	kg / lb	259 / 571	**Poids brut :** / **Gross Weight :**	kg / lb	13,496 / 29,754

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NOTTINGHAM
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NG4 2BH

Vendu à / Sold to :
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Date d'exp. / Shipping Date:	2021-11-08
Connaissement / Bill of Lading:	2626-133422-105902
Liste d'exp. / Shiplist:	105902
Équipement / Equipment :	7423A
Alliage (AA) / Alloy (AA) :	69271 (6061)
Produit / Product :	Aluminum Extrusion Ingot
Matériel Client / Customer Part:	
Dimension :	101 X 5500 MM 4.0 X 216.5 IN

Analyse en % du poids / Analysis in % of weight					Si	Fe	Cu	Mn	Mg	Cr	Zn	Ti	Bi	Ga
No d'échantillon de coulée Sample No of Drop	No Lot Lot No	Poids net (kg) Net Weight (kg)	Poids net (lb) Net Weight (lb)	Pièces Pieces	Na	Pb	Sn							

NO MORE THAN 2 CAST (HEAT) NUMBERS SHOULD BE SHIPPED AT THE SAME TIME/LOAD
USE HARD WOOD ONLY FOR BRACING
H.S. CODE 7601.20
ALUMINIUM ALLOYED INGOT
HYDROGEN VALUES:(21077401) = 0.128 (21089501) = 0.106 (21090101)= 0.13 (21100401)=0.13 (21095101)= 0.12 (21110101)=0.11

Paquets :	11	**Poids net :**	kg	13,237	**Pièces :**	110	**Tare :**	kg	259	**Poids brut :**	kg	13,496
Bundles :		**Net Weight :**	lb	29,183	**Pieces :**			lb	571	**Gross Weight :**	lb	29,754

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/ Ghita Ouaziz *Paul Cameron*
18.07.2022

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THE ANALYSES HERE ARE ACCURATE WITHIN COMMERCIAL LIMITS.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Luxfer Gas Cylinders Limited
Division of Luxfer Group Limited
Private Road 2
Colwick Industrial Estate
Nottingham
NG4 2BH
United Kingdom

Holds Certificate Number: FM 23214

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The design, development, manufacture, assembly and supply of aluminium alloy seamless high pressure gas cylinders, medical gas therapy devices, alternative fuel devices, and associated products and aluminium cold impact extrusion to customer order and specification requirements appropriate to the destination country

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1993-02-15
Latest Revision Date: 2022-07-19

Effective Date: 2022-05-19
Expiry Date: 2025-05-18

...making excellence a habit.™

EC CERTIFICATE OF AUTHORISATION

In accordance with the requirements of the Transportable Pressure Equipment Directive 2010/35/EU

This is to certify that the quality system of

Luxfer Gas Cylinders Limited
Colwick
Nottinghamshire
United Kingdom

has been assessed against the requirements of the ADR 2021 1.8.7.6 for inspections and test, and conforms to the requirements for the products shown below:

Production, Final Inspection & Testing of Seamless Aluminium Alloy High Pressure Gas Cylinders

Approval is subject to the continued maintenance of the quality system in accordance with the requirements of the ADR 2021 and continuing to comply with the EC Type Approval Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Nederland B.V. Notified Body Identification Number in accordance with the requirements of the specified Directive in relation to the products as identified above.

Certificate No.:	0343/BHM/TPED/COV0612076/1
Original Approval:	14 November 2000
Current Certificate:	19 May 2022
Certificate Expiry:	18 May 2025
Notified Body No. 0343	

S M Williams

S. M. Williams on behalf of LRQA Nederland B.V.

EC CERTIFICATE OF AUTHORISATION
0343/BHM/TPED/COV0612076/1

In accordance with the requirements of the Transportable Pressure Equipment Directive 2010/35/EU

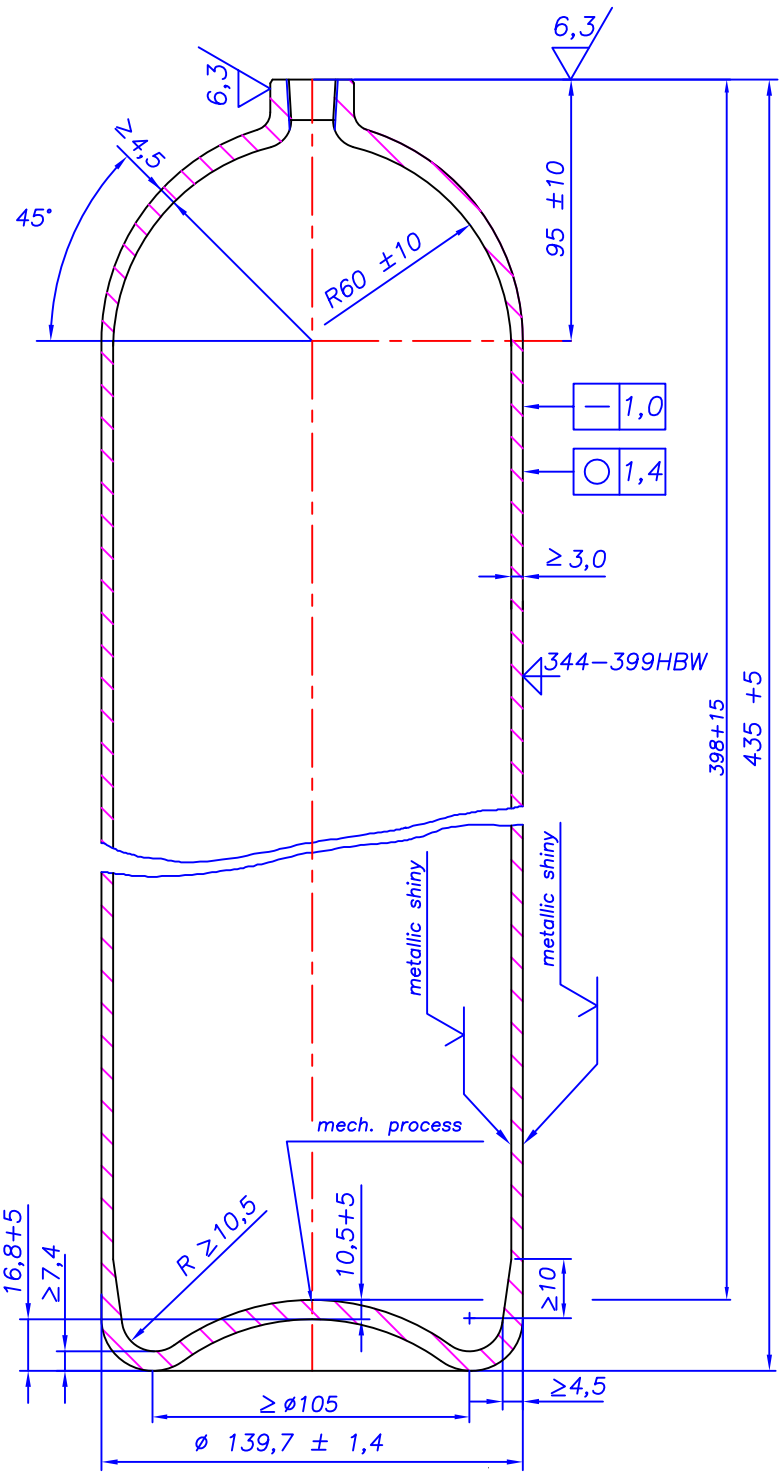
Products	Certificate Number	Issuing Notified Body	Expiry Date
Gas Cylinder 899/1/E	0343/TPED/ROT/COV1312186/05	LRQA NL B.V. (0343)	26/06/2023
Gas Cylinder 886/1/E	0343/TPED/ROT/COV1312186/06	LRQA NL B.V. (0343)	11/02/2023
Gas Cylinder 255/1/E	0343/TPED/ROT/COV1312186/07	LRQA NL B.V. (0343)	07/04/2024
Gas Cylinder 243/1/E	0343/TPED/ROT/COV1312186/08	LRQA NL B.V. (0343)	07/04/2024
Gas Cylinder 242/1/E	0343/TPED/ROT/COV1312186/09	LRQA NL B.V. (0343)	07/04/2024
Gas Cylinder 904/1/E	0343/TPED/ROT/COV1312186/10	LRQA NL B.V. (0343)	07/04/2024
Gas Cylinder 902/1/E	0343/TPED/ROT/COV1312186/11	LRQA NL B.V. (0343)	07/04/2024
Gas Cylinder 238/1/E	0343/TPED/ROT/COV1312186/14	LRQA NL B.V. (0343)	31/08/2024
Gas Cylinder - Part No. L3380N	0343/TPED/ROT/COV1512594/1	LRQA NL B.V. (0343)	22/11/2025
Gas Cylinder - Part No. P3378N	0343/TPED/ROT/COV1512254/1	LRQA NL B.V. (0343)	18/01/2026
Gas Cylinder - Part No. P3342I	0343/TPED/ROT/COV1512059/1	LRQA NL B.V. (0343)	19/01/2026
Gas Cylinder - Part No. P3347I	0343/TPED/ROT/COV1512059/2	LRQA NL B.V. (0343)	19/01/2026
Cylinder Family P7017N	0343/TPED/ROT/COV1619370/1	LRQA NL B.V. (0343)	26/10/2026
Cylinder Family P7018N	0343/TPED/ROT/COV1619370/2	LRQA NL B.V. (0343)	26/10/2026
Gas Cylinder – Part No. P3320N	0343/TPED/ROT/COV1711146/1	LRQA NL B.V. (0343)	13/03/2027
Gas Cylinder – Part No. P7030N	0343/TPED/ROT/COV1740229/1	LRQA NL B.V. (0343)	07/06/2027
Gas Cylinder – Part No. P7031N	0343/TPED/ROT/COV1740229/2	LRQA NL B.V. (0343)	07/06/2027
Gas Cylinder – Part No 708/1/N	0343/TPED/ROT/COV1740151/1	LRQA NL B.V. (0343)	23/07/2027
Gas Cylinder – Part No. 967/1/X	0343/TPED/ROT/COV1740218/1	LRQA NL B.V. (0343)	05/09/2027
Gas Cylinder – Part No. P3389I	0343/TPED/ROT/COV1723386/1	LRQA NL B.V. (0343)	12/11/2027
Gas Cylinder – Part No. P3391I	0343/TPED/ROT/COV1723386/2	LRQA NL B.V. (0343)	12/11/2027
Gas Cylinder – Part No. 669/1/I	0343/TPED/ROT/COV1711678/1	LRQA NL B.V. (0343)	20/12/2027
Gas Cylinder – Part No. 968/1/I	0343/TPED/ROT/COV1713735/1	LRQA NL B.V. (0343)	26/02/2028
Gas Cylinder – Part No. P7028N	0343/TPED/ROT/PRJ11066776/1	LRQA NL B.V. (0343)	15/10/2028
Gas Cylinder – Part No. P7033N	0343/TPED/ROT/PRJ11066781/1	LRQA NL B.V. (0343)	15/10/2028
Gas Cylinder – Part No. P7029N	0343/TPED/ROT/PRJ11066788/1	LRQA NL B.V. (0343)	15/10/2028
Gas Cylinder – Part No. P7034N	0343/TPED/ROT/PRJ11069176/1	LRQA NL B.V. (0343)	15/10/2028
Gas Cylinder – Part No. P7036N	0343/TPED/ROT/PRJ11069441/1	LRQA NL B.V. (0343)	15/10/2028
Gas Cylinder – Part No. P7038N	0343/TPED/ROT/PRJ11074699/1	LRQA NL B.V. (0343)	15/10/2028
Gas Cylinder – Part No. P7035N	0343/TPED/ROT/PRJ11069169/1	LRQA NL B.V. (0343)	24/10/2028
Gas Cylinder – Part No. P7034I	0343/TPED/ROT/PRJ1109995753/1	LRQA NL B.V. (0343)	12/05/2029
Gas Cylinder -- Part No. P7043N	0343/TPED/BHM/PRJ11091669/1	LRQA NL B.V. (0343)	21/05/2029
Gas Cylinder – Part No. P7046N	0343/TPED/BHM/PRJ11091669/2	LRQA NL B.V. (0343)	20/06/2029
Gas Cylinder – Part No. P7042N	0343/TPED/BHM/PRJ11091669/3	LRQA NL B.V. (0343)	13/08/2029
Gas Cylinder – Part No. 972/1/I	0343/TPED/ROT/PRJ1110016683/1	LRQA NL B.V. (0343)	15/01/2030
Gas Cylinder – Part No. 973/1/X	0343/TPED/ROT/PRJ11100226309/1	LRQA NL B.V. (0343)	27/01/2030
Gas Cylinder – Part No. 951/1/I	0343/TPED/BHM/PRJ11100294817/1	LRQA NL B.V. (0343)	03/02/2031
Gas Cylinder – Part No. 955/1/I	0343/TPED/BHM/PRJ11100299876/1	LRQA NL B.V. (0343)	03/02/2031
Gas Cylinder – Part No. 975/1/I	0343/TPED/BHM/PRJ11100265024/1	LRQA NL B.V. (0343)	11/02/2031
Gas Cylinder – Part No. 713/1/N	0343/TPED/BHM/PRJ11100258364/1	LRQA NL B.V. (0343)	24/02/2031
Gas Cylinder – Part No. 893/1/I	0343/TPED/BHM/PRJ11100297135/3/047	LRQA NL B.V. (0343)	18/04/2031
Gas Cylinder – Part No. 950/1/I	0343/TPED/BHM/PRJ11100297135/3/053	LRQA NL B.V. (0343)	18/04/2031
Gas Cylinder – Part No. P3305I	0343/TPED/BHM/PRJ11100297135/3/045	LRQA NL B.V. (0343)	28/04/2031
Gas Cylinder – Part No. L3355I	0343/TPED/BHM/PRJ11100297135/3/081	LRQA NL B.V. (0343)	20/05/2031
Gas Cylinder – Part No. 953/1/I	0343/TPED/BHM/PRJ11100297016/3/083	LRQA NL B.V. (0343)	03/06/2031

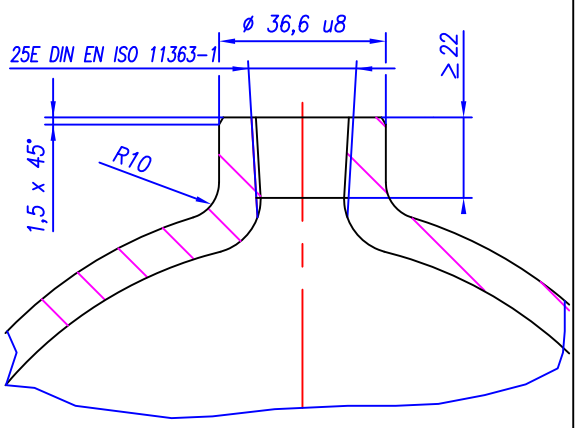
Products	Certificate Number	Issuing Notified Body	Expiry Date
Gas Cylinder – Part No. 898/1/N	0343/TPED/BHM/PRJ11100297135/3/077	LRQA NL B.V. (0343)	23/06/2031
Gas Cylinder – Part No. 897/1/I	0343/TPED/BHM/PRJ11100297135/3/071	LRQA NL B.V. (0343)	06/07/2031
Gas Cylinder – Part No. L3107N	0343/TPED/BHM/PRJ11100297135/3/121	LRQA NL B.V. (0343)	03/08/2031
Gas Cylinder – Part No. P3359YI	0343/TPED/BHM/PRJ11100297135/3/148	LRQA NL B.V. (0343)	12/09/2031
Gas Cylinder – Part No. L3104N	0343/TPED/BHM/PRJ11100297135/3/124	LRQA NL B.V. (0343)	13/09/2031
Gas Cylinder – Part No. 272/1/N	0343/TPED/BHM/PRJ11100297135/3/134	LRQA NL B.V. (0343)	13/09/2031
Gas Cylinder – Part No. 941/1/I	0343/TPED/BHM/PRJ11100297135/3/144	LRQA NL B.V. (0343)	13/09/2031
Gas Cylinder – Part No. L3121N	0343/TPED/BHM/PRJ11100297135/3/118	LRQA NL B.V. (0343)	16/09/2031
Gas Cylinder – Part No. 875/1/N	0343/TPED/BHM/PRJ11100297135/3/136	LRQA NL B.V. (0343)	23/09/2031
Gas Cylinder – Part No. P3320I	0343/TPED/BHM/PRJ11100297135/3/142	LRQA NL B.V. (0343)	23/09/2031
Gas Cylinder – Part No. P2806Z	01/GB/218 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. P2871Z	01/GB/219 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. L3067Z	01/GB/220 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. P2810Z	01/GB/221 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. P2851Z	01/GB/222 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. L2889Z	01/GB/223 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. L2815Z	01/GB/224 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. P3136Z	01/GB/225 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. P3068Z	01/GB/226 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. L3178Z	01/GB/227 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. 285/1/Q	01/GB/228 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. 834/1/Q	01/GB/230 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. 424/1/Q	01/GB/231 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. L2922G	01/GB/232 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. 605/1/Q	01/GB/234 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. P2802Z	01/GB/235 Index 1 – Rev. 0	Apragaz (0029)	12/10/2031
Gas Cylinder – Part No. 818/1/Q	01/GB/297 Index 1 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. 868/1/Q	02/GB/318 Index 1 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. 656/1/Q	02/GB/320 Index 1 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. L2921G	03/GB/567 Index 1 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. L3055G	03/GB/691 Index 1 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. P3325N / P3325I	09/GB/1765 Index 3 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. P3337N / P3337I	09/GB/1863 Index 2 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. P3338N / P3338I	09/GB/1864 Index 3 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. P3339I / L3379I, P3382N	09/GB/1865 Index 4 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. P3340N / P3340I, P3394I	09/GB/1866 Index 3 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. L3347N / P3341I, P3341N	09/GB/1867 Index 3 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. P3342N / P3342I	09/GB/1868 Index 2 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. P3330N / P3330I	09/GB/1872 Index 2 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. P3332N / P3332I	09/GB/1873 Index 2 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. P3333N / P3333I	09/GB/1874 Index 2 – Rev. 0	Apragaz (0029)	25/10/2031
Gas Cylinder – Part No. P3230N	0343/BHM/TPED/PRJ11100315925/2	LRQA NL B.V. (0343)	16/01/2032
Gas Cylinder – Part No. P3124N	0343/BHM/TPED/PRJ11100315933/2	LRQA NL B.V. (0343)	16/01/2032

Schedule Issue: 02
Date of Schedule Issue: 19 May 2022
Notified Body No. 0343

S. M. Williams on behalf of LRQA Nederland B.V.

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

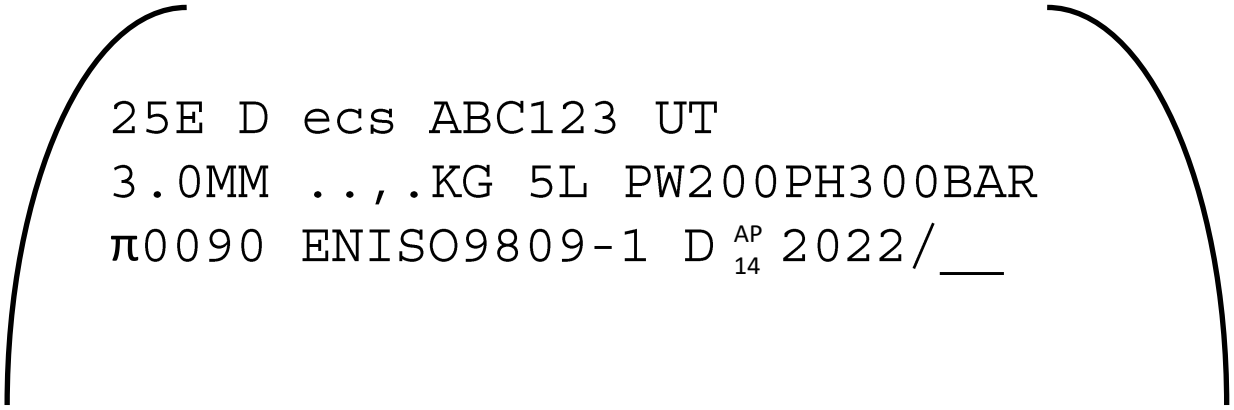
(regulation) DIN EN ISO 9809-1:2010/ ISO 9809-1:2010
(RL 2010/35/EU) 0090/EN49/12

(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

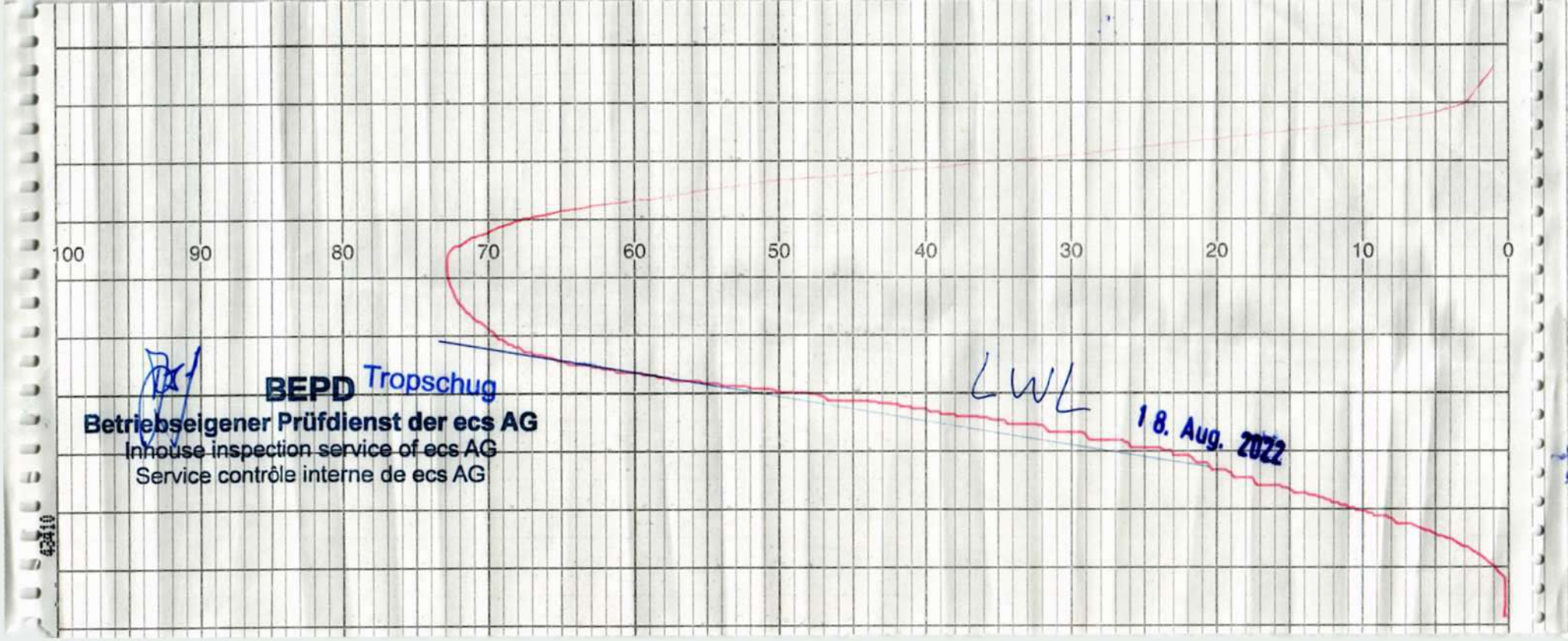
2. Bestätigung über die Einhaltung der technologischen Parameter
Compliance with technical parameters
Conformité des caractéristique techniques

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

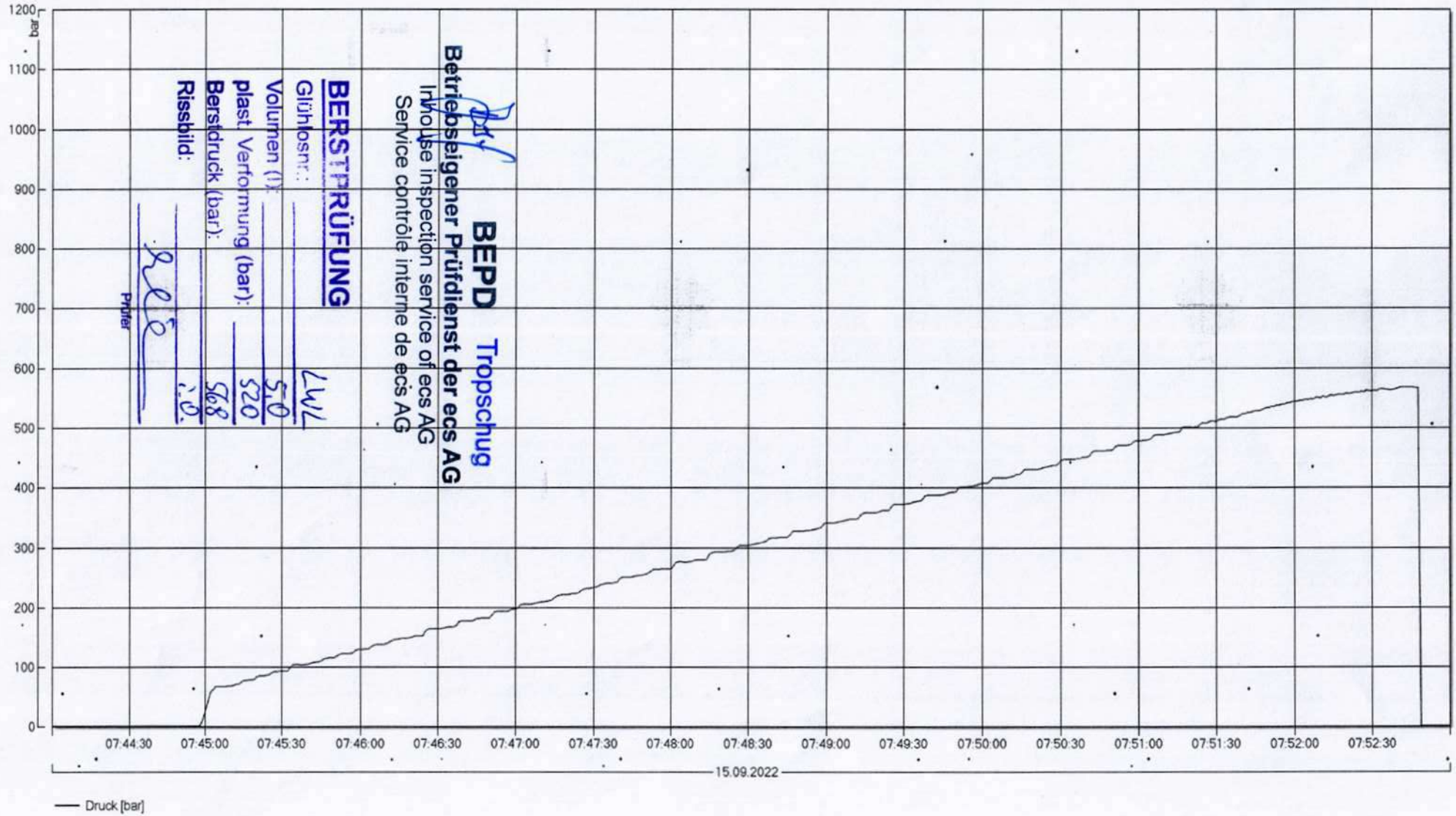
BEPD Tropschug
Betriebseigener Prüfdienst der ecs AG
Inhouse inspection service of ecs AG
Service contrôle interne de ecs AG

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

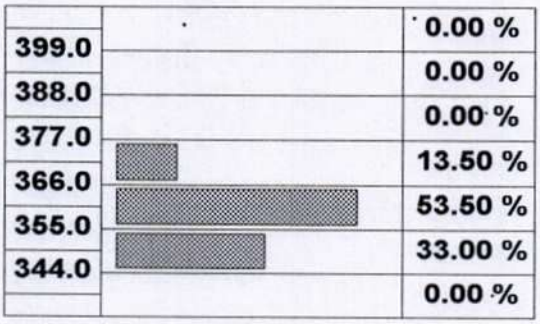
Chargen-Nr.	
SB-Nr.	LWL
Volumen	5,0
Fl.-Beh.-Typ	
Schicht	1
Anlagenfahrer	Felsberg
Prüfmethode	HB 30
Härteminimum	344
Härtemaximum	399

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

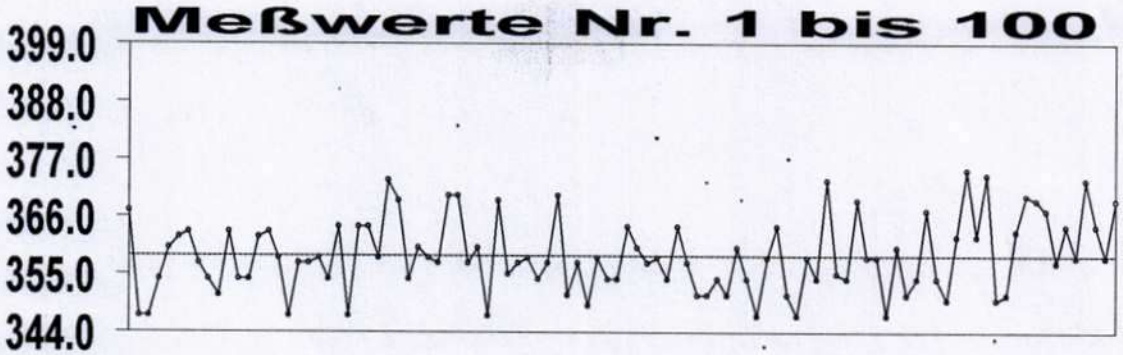
Statistikwerte :[HB 30]

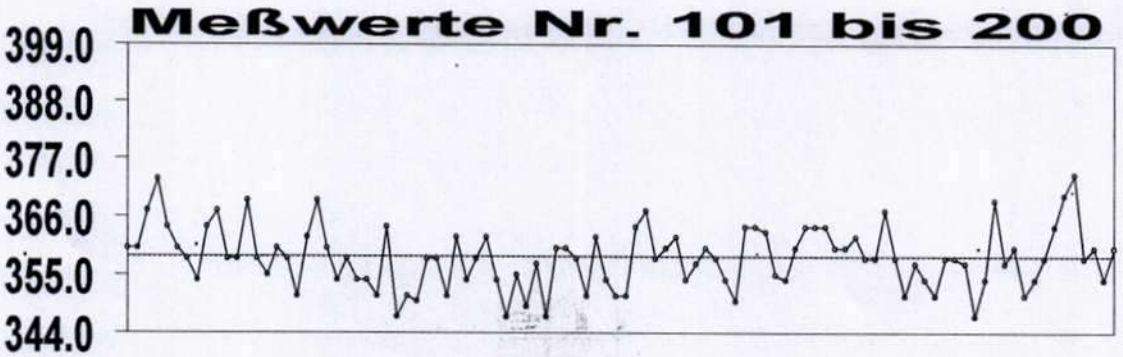
Gesamtanzahl	:	200
Anzahl in Grenzen	:	200
Anzahl zu weich	:	0
Anzahl zu hart	:	0
Anzahl ST	:	200
kleinster Wert	:	347.0
größter Wert	:	375.0
Xquer	:	358.380
Standardabweichung	:	6.434

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

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

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

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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

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

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

Vizualizati mai multe imagini

- 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

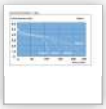
Gaz:	O_2, Aer, N_2O, CO_2, O_2/N_2O
Presiune intrare:	Pana la 300 bar
Presiune iesire:	3,6 - 5,5 bar
Gama de presiune*:	
de la 0 la 2 l/min:	0/ 0,1 / 0,2 / 0,3 / 0,4 / 0,5 / 0,6 / 0,7 / 0,8 / 1 / 1,5 / 2
de la 0 la 6 l/min:	0/ 0,25 / 0,5 / 0,75 / 1 / 1,5 / 2 / 2,5 / 3 / 4 / 5 / 6
de la 0 la 25 l/min:	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

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.

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.

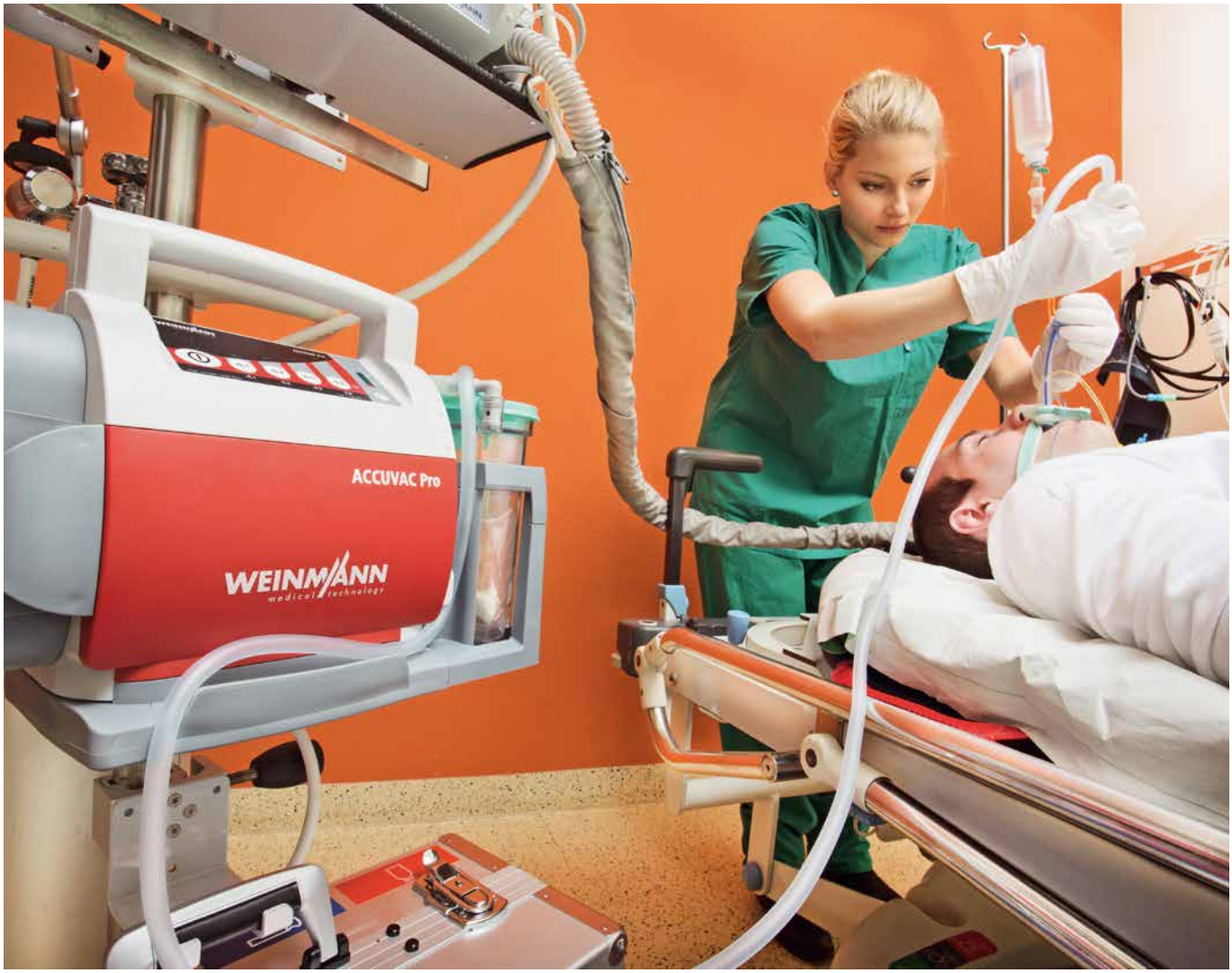
Conformity declaration and marking of product

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

ACCUVAC Pro suction device

Experience at its best – for Professional Demands



ACCUVAC Pro

Experience at its best – for professional demands

The first life-saving step involves clearing the patient's airways from obstructions so that effective ventilation can be administered. In an emergency situation the patient's survival depends on keeping the airways clear. ACCUVAC Pro ensures free and clear airways by suctioning the mouth and throat, endotracheal or bronchial areas. The pump's high suction capacity and its easy handling assist medical personnel in carrying out this effective and proven patient procedure in professional emergency medical services.

Broad application range, flexible operation

With the choice of four pre-defined suction levels, the user can adjust the suction capacity to every situation. ACCUVAC Pro can be used on babies, children and adults. In addition to suctioning airways, ACCUVAC Pro also deflates vacuum splints and mattresses.

Your benefits at a glance

- Variable uses
- Safe and hygienic
- Simple operation, robust
- EN 1789-compliant, air worthy as per RTCA DO-160G

Convenient operation, broad application spectrum

- High suction capacity of about 34 liters/minute at -0.8 bar (at device inlet)
- Rechargeable battery: user can easily change battery without tools
- Modern lithium-ion rechargeable battery with greater run time of more than 60 minutes
- Four pre-defined vacuum levels can be selected by user
- Automatic function check with rapid visual and acoustic feedback
- Safe secretion collection in auto-clavable reusable secretions canister with disposable bacteria filter and overflow protection or disposable Serres® suction bag with integrated bacteria filter
- Robust housing made of impact-resistant materials
- Non-tip housing with low center of gravity

Ideal operation in everyday medical services

- Optimum accommodation of suction tube in holder on side of device
- Single-handed release from the wall mounting with the press of a button
- Compatible with existing ACCUVAC wall mounting
- Optionally available: large accessories bag, protective bag and/or shoulder strap

For every patient and every emergency

- Suctioning of secretions and food particles
- Endotracheal and bronchial suction
- Particularly suitable for pre-hospital care
- Deflate vacuum splints and mattresses
- Suitable for use on babies, children and adults

Safety and reliability day after day

In the event of a malfunction, you can read out the service files from your ACCUVAC Pro and send them to WEINMANN Emergency. At best, the data are enough for our specialists to provide a remote diagnosis and work with you to resolve the problem. If not, we will take a closer look at your device and, as needed, we will give you a replacement device to use while yours is out of service.

Service Hotline
+49 40 88 18 96 122

Service data: ACCUVAC Pro

Manufacturer's warranty	2 years
Safety check interval	no check required
Maintenance schedule	no maintenance required
Function check	automatic
Time required for function check	about 15 seconds
Battery change	simple, from outside device, no tools required
Rechargeable battery	no maintenance, no calibration required
Deep discharge protection for battery	✓
Protection from electrical surge and reverse polarity	✓
Conversion of disposable system/ reusable system	simple, without tools
Software update can be made by operator/user	✓
Remote diagnosis of device malfunction	✓

Intuitive Operation Ensures Safety

1. Holder for suction tube
for ideal storage

2. Four pre-defined suction levels
quick push-button selection

3. Backlit
to make suction levels visible in poor lighting conditions

4. Release for wall mounting
single-handed release with press of button

5. Battery compartment cover
can be opened without tools for fast and easy access to battery

6. Rechargeable battery
modern lithium-ion battery with longer service life and rapid charging

7. Device base with tube guide

8. Automatic function check
with quick visual and acoustic feedback

9. Canister holder
impact-resistant materials increase safety for the canister systems

10. Secretions canister Serres®, 1000 ml
with disposable suction bag, integrated bacteria filter and solidifying agents. When the bag is full, ACCUVAC Pro stops automatically

Technical Data

ACCUVAC Pro

Product class as per Directive 93/42/EEC	IIa
RoHS-conformity as per Directive 2011/65/EU (RoHS II)	Yes
Classification as per EN ISO 10079-1	High vacuum/high flow
Standards used	EN 60601-1, EN 60601-1-11, EN 60601-1-12, EN ISO 10079-1, EN 1789, RTCA DO-160 G
Dimensions (W x H x D)	• with canister system 370 x 277 x 146 mm • with canister system + accessories bag 370 x 277 x 152 mm
Weight	• Device with battery, no canister system and holder 3.65 kg • Reusable canister system with holder 1.00 kg • Disposable canister system with holder 0.65 kg
Temperature range: Operation Transport/storage	-5 °C to +50 °C -40 °C to +70 °C
Maximum current consumption	3.8 A
Rated voltage	12 V DC nominal (min. 10 V, max. 15 V)
Suction capacity at device inlet (without canister system) at -0.8 bar, fully charged battery and 21 °C/1013 hPa	34 liters/min
Suction capacity at device inlet to reusable canister system at -0.8 bar, fully charged battery and 21 °C/1013 hPa	30 liters/min
Vacuum settings	Pre-defined levels: -0.1 bar, -0.2 bar, -0.5 bar and -0.8 bar, electronically regulated
Type of operation	S2 60 min
Degree of protection	IP34D
Type of rechargeable battery	L-ion
Rechargeable battery	• Charging time: Battery status 80%: 2 hrs, 40 min (at 20 °C while not in use); Battery status 100 %: about 4 hrs • Service life: about 500 charging cycles • Battery operating time: 60 min (during continuous operation with fully charged/new battery)
Volume of secretions canister	1000 ml
Reusable suction tube	10 mm ID, 1300 mm long
Disposable suction tube	7 mm ID, 1800 mm long

CE 0124

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

Designed in Germany

Select your preferred ACCUVAC Pro combination – designed to meet your needs:

ACCUVAC Pro with disposable canister system, WM 11605

ACCUVAC Pro with reusable canister system* WM 11600

ACCUVAC Pro with disposable canister system with accessories bag, WM 11645

ACCUVAC Pro with reusable canister system* with accessories bag, WM 11640

Combine your ACCUVAC Pro with additional accessories from page 6

*Please note that the reusable canister system is equipped with a disposable bacteria filter.

Accessories and Replacement Parts

Accessories

1. Protective bag WM 11692
(cannot be combined with accessories bag)

2. Shoulder strap WM 11693

3. 12-V connection cable WM 10650

4. Power supply unit und charger WM 2620
for 100V to 240V alternating current to ACCUVAC device plug, including power cable in compliance with EN 50075 (Europlug)

5. Wall mounting for ACCUVAC WM 15208
including installation set

6. Holding plate for standard hospital rails WM 15845

7. Attachment set with WM 15805
two adapters for standard hospital rails

8. Wall mounting for power supply unit WM 15844
and charger

9. Installation set pole bracket WM 15806
dia. 19 mm - 40 mm

10. Conversion set for reusable canister system, WM 17820
consisting of:
- Set, reusable canister system (WM 17821)
- Holder for reusable canister system (WM 11654)

11. Conversion set for disposable canister system, WM 17825
consisting of:
- Holder for disposable canister system (WM 11754)
- Vacuum tube for Serres® secretions canister (WM 11761)
- Serres® secretions canister, complete (WM 10790)

12. Conversion kit for accessories bag, WM 17829
consisting of:
- Accessories bag (WM 11691)
- Battery compartment cover for accessories bag (WM 11614)

Consumables

13. Serres® suction bag 1000 ml, with WM 17800
hydrophobic filter and solidifying agent
(Packaging unit: 32 items in carton)

14. Disposable suction tube with fingertip WM 10778
control for use with disposable system,
180 cm long, 7 mm ID, also available in
sets of 10, 20, 32 and 50 tubes

15. Reusable suction tube 130 cm long, WM 10662
10 mm ID, also available in sets of
10, 20, and 50 tubes

16. Fingertip control for reusable suction tube WM 10666
10 mm ID, also available in sets of
10, 20 and 50 pieces

17. Set of 10 disposable bacteria filters WM 17830
for reusable secretions canister

Replacement Parts for Reusable System

1.	Upper part of secretions canister cover	WM 11657
2.	Filter holder	WM 11661
3.	O-Ring for filter holder	WM 11663
4.	Disposable bacteria filter	
5.	Lower part of secretions canister cover	WM 11658
6.	Ball float valve	WM 11662
7.	Reusable secretions canister 1000 ml	WM 11653
8.	Reusable suction tube 10 mm ID	WM 10662
9.	Fingertip control for reusable suction tube 10 mm ID	WM 10666
10.	Holder for reusable canister system	WM 11654
•	Secretions canister cover, complete, consisting of replacement parts 1 – 6	WM 17822
•	Set, reusable canister system consisting of replacement parts 1 – 9	WM 17821
•	Conversion set for reusable canister system consisting of replacement parts 1 – 10	WM 17820

Replacement Parts for Serres® Disposable System

•	Serres® secretions canister, complete, consisting of: - Secretions canister, 1000 ml (WM 10775) - Suction bag - Disposable suction tube with fingertip control (WM 10778)	WM 10790
•	Serres® secretions canister, 1000 ml	WM 10775
•	Vacuum tube for Serres® secretions canister	WM 11761
•	Holder for disposable canister system	WM 11754
•	Set disposable canister system, consisting of: - Vacuum tube for Serres® secretions canister (WM 11761) - Serres® secretions canister, complete (WM 10790)	WM 17826
•	Angled connector for Serres® canister, reusable	WM 10799

Replacement Parts for ACCUVAC Pro

•	Set, catch release	WM 17827
•	Lithium-ion rechargeable battery	WM 11603
•	Battery compartment cover (without eyelets for accessories bag)	WM 11604
•	Holder for suction tube	WM 11664
•	Device base	WM 11677

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 Designed in Germany WEINMANN-Emergency.com

11 Anexă

11.1 Date tehnice

11.1.1 Date tehnice ale aparatului

Specificații	ACCUVAC Pro	ACCUVAC Lite
Clasa de produs conform Directivei 93/42/CEE	IIa	
Dimensiuni (L x H x P) împreună cu sistemul de recipiente	370 mm x 277 mm x 146 mm	
Greutate: Aparat cu acumulator/fără sistem de recipiente şi locaşul acestuia Sistem de recipiente refolosibil împreună cu locaşul acestuia Sistem de recipiente de unică folosință împreună cu locaşul acestuia	 3,65 kg 1,00 kg 0,65 kg	 4,6 kg 1,00 kg 0,65 kg
Funcționare: Domeniu de temperatură Umiditate aer: Presiune aer	 -5°C până la +50°C 5% până la 95% umiditate relativă fără condens 540 hPa până la 1100 hPa	
Transport/depozitare: Domeniu de temperatură Umiditate aer: Presiune aer	 -40°C până la +70°C 5% până la 95% umiditate relativă fără condens 540 hPa până la 1100 hPa	
Procesul de încărcare: Domeniu de temperatură Umiditate aer: Presiune aer	 0°C până la +40°C 5% până la 95% umiditate relativă fără condens 540 hPa până la 1100 hPa	 -5°C până la +50°C 5% până la 95% umiditate relativă fără condens 540 hPa până la 1100 hPa
Altitudine maximă de lucru	5000 m (peste nivelul mării)	
Grad de murdărire	Clasa 1	
Categorie supratensiune	II	
Consum maxim de putere	45 W	
Consum maxim de curent	3,8 A	4,3 A
Tensiune nominală	12 Vcc nominal (min. 10 V, max. 15 V) la interfața de încărcare, prin alimentatorul de rețea cu încărcător sau prin cablul de legătură de 12 V pentru autovehicul	
Pompă	Pompă de vid (pompă cu membrană) cu 1 cap	

WM 68174 06/2015

Specificații	ACCUVAC Pro	ACCUVAC Lite
Capacitate de aspirație la intrarea aparatului (fără sistem de recipiente) la -0,8 bar, acumulator complet încărcat şi 21°C/1013 hPa (determinată cu recipient tampon de 1 litru)	34 l/min ± 4 l/min	26 l/min ± 4 l/min
Capacitate de aspirație la intrare sistem de recipiente refolosibil la -0,8 bar, acumulator complet încărcat şi 21°C/ 1013 hPa	30 l/min ± 3 l/min	23 l/min ± 3 l/min
Vid maxim obtenabil	0,8 bar, respectiv 80% din presiunea atmosferică	
Reglarea nivelului de vid	Pe trepte predefinite: -0,1 bar, -0,2 bar, -0,5 bar şi -0,8 bar, cu reglaj electronic	Cu butonul regulator pentru reglaj continuu: -0,1 bar până la -0,8 bar
Indicator vid	Prin LED-uri pe panoul de comandă	Manometru până la maximum -1 bar, clasă de precizie 2,5 (2,5%)
Afişaj	Prin LED-uri pe panoul de comandă: pornit/oprit, nivel vid selectat, nivel vid actual, indicator stare acumulator, avertizare (LED de stare roşu)	Prin LED-uri pe panoul de comandă: pornit/oprit, indicator stare acumulator, avertizare (LED de stare roşu)
Ciclu de pornire (regim de scurtă durată)	60 min pornit, 120 min oprit	45 min pornit, 90 min oprit
Nivel de zgomot: nivel mediu presiune acustică la distanță de 1 m şi la -0,8 bar	<70 dB(A)	
Mod de fixare	Compatibil cu suportul de perete WM 15208	
Clasificare conform EN 60601-1: • tip de protecție contra electrocutării • grad de protecție contra electrocutării	Clasă de protecție II (la alimentare din rețea şi din acumulator) Componentă de aplicație de tip BF	
Grad de protecție contra: • pătrunderii corpurilor solide • pătrunderii prafului • pătrunderii apei cu efect dăunător	IP34D	
Clasificare conform EN ISO 10079-1	High vacuum/high flow	
Cod UMDNS	Aparat de aspirație 15-016, cazuri de urgență	
Cod GMDN	36616 Suction unit, transport and emergency	
Controale tehnice de siguranță repetate (STK, numai în Germania)	Nu sunt necesare	

CE 0124

Ne rezervăm dreptul de a efectua modificări constructive

WM 68174 06/2015

11.1.2 Date tehnice acumulator

Specificații	ACCUVAC Pro	ACCUVAC Lite
Tip	Li-Ion 4IMR 19/66-2 BM18650Z3	Plumb Panasonic LC-R123R4PG
Dimensiuni (L x H x P)	43 mm x 73 mm x 75 mm	67 mm x 134 mm x 67 mm
Greutate	0,4 kg	1,15 kg
Capacitate nominală	Minimum 4,3 Ah	3,4 Ah
Tensiune nominală	14,8 V nominal	12 V nominal
Timp de încărcare	Stare acumulator 80%: 2 h 40 min la 20°C fără funcționare aparat Stare acumulator 100%: cca. 4 h Comutare automată pe încărcare de întreținere	Stare acumulator 80%: 2,45 h Stare acumulator 100%: 14 h Comutare automată pe încărcare de întreținere
Intervale de încărcare în caz de depozitare mai îndelungată	La fiecare 6 luni	La fiecare 3 luni
Durata de funcționare a acumulatorului în regim neîntrerupt cu acumulator încărcat complet/nou (>20 l/min, reglaj -0,8 bar)	60 min la -5°C 60 min la +21°C 30 min la +50°C	23 min la -5°C 40 min la +21°C 40 min la +50°C
Durată de viață	Cca. 500 cicluri de încărcare	400 cicluri de încărcare în cca. 3 ani
Afişaj	Indicator stare de încărcare în funcționare şi la încărcare	

Durată tipică de funcționare a acumulatorului*	ACCUVAC Pro	ACCUVAC Lite
-0,2 bar	145 min	40 min
-0,5 bar	100 min	40 min
-0,8 bar	60 min	40 min

* Măsurată la +21°C, utilizare neîntreruptă, fără încărcarea acumulatorului şi la circulație liberă a aerului.

WM 68174 06/2015

11.1.3 Date tehnice pentru sistemul de recipiente refolosibil

Specificații	Sistemul de recipiente refolosibil
Volum	1000 ml
Racord pentru furtun de aspirație refolosibil	Ø 10 mm interior
Furtun de aspirație refolosibil Diametru Lungime	 Ø 10 mm interior 1300 mm
Racord la aparatul de aspirație	Racord direct (fără furtun intermediar)
Filtru de bacterii	Cartuş de filtru hidrofob de bacterii pentru utilizare în capacul recipientului pentru secreții, articol de unică folosință
Eficiența de separare a filtrului de bacterii	>99,9%

11.1.4 Date tehnice pentru sistemul de recipiente de unică folosință

Specificații	Sistem de recipiente de unică folosință
Volum	1000 ml
Racord pentru furtun de aspirație de unică folosință	Ø 7 mm interior
Furtun de aspirație de unică folosință Diametru Lungime	 Ø 7 mm interior 1800 mm
Racord la aparatul de aspirație	Prin furtun de vid (furtun intermediar)
Filtru de bacterii	Integrat în punga de aspirație Serres®

11.1.5 Date tehnice pentru alimentatorul de rețea cu încărcător

Specificații	Alimentator de rețea cu încărcător
Clasa de produs conform Directivei 93/42/CEE	I
Dimensiuni (L x H x P):	130 mm x 36 mm x 60 mm
Greutate	280 g
Funcționare: Domeniu de temperatură Umiditate aer: Presiune aer	 0°C până la +40°C 10% până la 90% umiditate relativă fără condens 700 hPa până la 1100 hPa

WM 68174 06/2015

Specificații	Alimentator de rețea cu încărcător
Transport/depozitare: Domeniu de temperatură Umiditate aer: Presiune aer	 -40°C până la +70°C 10% până la 95% umiditate relativă fără condens 700 hPa până la 1100 hPa
Tensiune de alimentare	100 Vca până la 240 Vca 50 Hz până la 60 Hz
Consum maxim de curent	1,1 A
Valori nominale ieşire	13,8 Vcc 3,5 A
Clasificare conform EN 60601-1: • tip de protecție contra electrocutării • grad de protecție contra electrocutării	 Clasă de protecție II Componentă de aplicație de tip CF
Grad de protecție contra • pătrunderii corpurilor solide • pătrunderii prafului • pătrunderii apei cu efect dăunător	IP40
Lungime cablu de ieşire	1,8 m
Lungime cablu de rețea	Cca. 2 m

CE

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11.1.6 Date tehnice pentru cureaua de purtare

Specificații	Curea de purtare
Sarcină maximă	7 kg

WM 68174 06/2015

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

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

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810024**

Certificate Holder: **WEINMANN Emergency Medical Technology GmbH + Co. KG**
Frohbösestraße 12
22525 Hamburg
Germany

including the locations according to annex

Scope: Design and development, production, distribution and servicing of medical devices and digital services for emergency and transport medicine

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-07-01 until 2025-06-30.

2022-03-22

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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