AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
				2813		3a				
DM000344455	INHALATOR CU COMPRESOR PENTRU TERAPIE RESPIRATORIE		AP701A - HOSPYNEB PROFESSIONAL	28134	Italia	3A HEALTH CARE S.R.L.	TETIS INTERNATIONAL CO S.R.L.	Rg04-000080	29-03-2022	

Содержит([Producatorul], '3a') И Содержит([Nr. catalog], '2813')

Очистить

Digitally signed by Vidiborschii Vladimir
Date: 2022.09.15 10:23:50 EEST
Reason: MoldSign Signature
Location: Moldova

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
	mas		om-6n			uzum				
DM000257669	MASĂ PENTRU OPERAȚII		OM-6N		Turcia	UZUMCU TIBBI CIHAZ VE MEDIKAL GAZ SISTEMLERI SAN. VE TIC. A.S	Î.C.S. EYECON MEDICAL S.R.L.	Rg04-000313	09-12-2019	
DM000257893	MASĂ PENTRU OPERAȚII		OM-6N		Turcia	UZUMCU TIBBI CIHAZ VE MEDIKAL GAZ SISTEMLERI SAN. VE TIC. A.S	MEDICA SENS S.R.L	Rg04-000313	09-12-2019	
DM000192522	MASĂ PENTRU OPERAȚII		OM-6N		Turcia	UZUMCU TIBBI CIHAZ VE MEDIKAL GAZ SISTEMLERI SAN. VE TIC. A.S	TETIS INTERNATIONAL CO S.R.L.	A07.PS-01.Rg04-378	26-12-2018	

Содержит([Producatorul], 'uzum') И Содержит([Denumire], 'mas') И Содержит([Model], ...

Очистить

MORETTI S.p.A.
Via Bruxelles, 3 – Meleto
52022 Cavriglia (Arezzo)
Tel. +39 055 96 21 11
Fax. +39 055 96 21 200

info@morettispa.com
www.morettispa.com
P. IVA 00306090515
Meccanografico AR 005370

Reg. Imp. Arezzo 3932
R.E.A. 68869
Cap. Soc. € 500.000
C/C Postale 13682521

DICHIARAZIONE DI CONFORMITA'

CE

Ai sensi della direttiva 93/42/CEE

La MORETTI SpA dichiara sotto la sua esclusiva responsabilità che i prodotti fabbricati ed immessi in commercio dalla stessa MORETTI SpA. e facenti parte della famiglia

OTOSCOPI - OFTALMOSCOPI

Sono conformi alle disposizioni applicabili della direttiva

93/42/CEE sui DISPOSITIVI MEDICI
così come modificata dalla direttiva 2007/47

Ed ai seguenti standard internazionali

UNI CEI EN ISO 14971:2009 Applicazione della gestione dei rischi dei dispositivi medici
UNI EN 980:2009 Simboli grafici utilizzati per l'etichettatura dei dispositivi medici

A tal scopo la MORETTI SpA. garantisce e dichiara sotto la propria esclusiva responsabilità quanto segue :

1. *I dispositivi in oggetto soddisfano i requisiti essenziali richiesti dall'allegato I° della direttiva 93/42/CEE come prescritto dall'allegato VII° della suddetta direttiva.*
2. *L'elenco completo dei dispositivi in oggetto viene indicato nell'Allegato A della presente dichiarazione.*
3. *I dispositivi in oggetto NON SONO STRUMENTI DI MISURA.*
4. *I dispositivi in oggetto NON SONO DESTINATI AD INDAGINI CLINICHE.*
5. *I dispositivi in oggetto vengono commercializzati in confezione NON STERILE.*
6. *I dispositivi in oggetto sono da considerarsi come appartenenti alla classe I°.*
7. *La MORETTI SpA mantiene e mette a disposizione delle Autorità Competenti, per un periodo di almeno 8 anni dalla data di fabbricazione dell'ultimo lotto, la documentazione tecnica comprovante la conformità alla Direttiva 93/42/CEE.*

Cavriglia, 16/01/2012

MORETTI SpA

Allegati :
Allegato A – Elenco dispositivi medici

ALLEGATO A – ELENCO DISPOSITIVI MEDICI

Famiglia : ***OTOSCOPI - OFTALMOSCOPI***

Codice	***Descrizione***
DMV520	*OTOSCOPIO MINI A FIBRE OTTICHE DIMED*
DMV525	*OFTALMOSCOPIO MINI A FIBRE OTTICHE DIMED*
DMV530	*OTO-OFTALMO MINI FIBRE OTTICHE DIMED*
DMV540	*OTOSCOPIO MINI A LUCE CONVENZIONALE DIMED*

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-535

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

İNSPİTAL MEDİKAL TEKNOLOJİ ANONİM ŞİRKETİ

Karaoğlan Mahallesi Karaoğlan Küme Evleri No:745 Gölbaşı/ Ankara, Turkey

Products: Flowmeters, Anaesthetic Gas Scavenging (AGSS) System, Area Gas Control Panels, Pipelines and Stations for Medical Gases, Pipelines and Stations for Vacuum, Patient Bed Head Unit, Pendant Unit, Anaesthetic Gas Scavenging Terminal Unit and Probe, Jacks and Outlet for Compressed Medical Gas, Jacks and Outlet for Vacuum, Pressure Regulator with Flowmeter, Manifold and Line Pressure Regulators, Pressure Regulator, Vacuum Regulator, Surgical Suction Unit, Central Vacuum System, Medical Copper Tubings, Electrosurgical Unit

The products defined at the enclosure which is the part of this certificate and contains four page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5220.03
Date of first issue: 02 August 2018
Date of last issue: 21 April 2021
Revision Number: 02
Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

21 April 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-18-535, Revision Number: 02

Concerned medical devices;

Product: Flowmeters
Model: FM20.11, FM20.21, FM20.31, FM20.41, FM20.51, FM20.61, FM20.71, FM20.12, FM20.22, FM20.32, FM20.42, FM20.52, FM20.62, FM20.72, FM20.13, FM20.23, FM20.33, FM20.43, FM20.53, FM20.63, FM20.73, FM20.14, FM20.24, FM20.34, FM20.44, FM20.54, FM20.64, FM20.74, FM20.15, FM20.25, FM20.35, FM20.45, FM20.55, FM20.65, FM20.75, FM20.16, FM20.26, FM20.36, FM20.46, FM20.56, FM20.66, FM20.76, FM20.17, FM20.27, FM20.37, FM20.47, FM20.57, FM20.67, FM20.77, FM20.18, FM20.28, FM20.38, FM20.48, FM20.58, FM20.68, FM20.78, FM21.11, FM21.21, FM21.31, FM21.41, FM21.51, FM21.61, FM21.71, FM21.12, FM21.22, FM21.32, FM21.42, FM21.52, FM21.62, FM21.72, FM21.13, FM21.23, FM21.33, FM21.43, FM21.53, FM21.63, FM21.73, FM21.14, FM21.24, FM21.34, FM21.44, FM21.54, FM21.64, FM21.74, FM21.15, FM21.25, FM21.35, FM21.45, FM21.55, FM21.65, FM21.75, FM21.16, FM21.26, FM21.36, FM21.46, FM21.56, FM21.66, FM21.76, FM21.17, FM21.27, FM21.37, FM21.47, FM21.57, FM21.67, FM21.77, FM21.18, FM21.28, FM21.38, FM21.48, FM21.58, FM21.68, FM21.78

Product: Area Gas Control Panels
Model: GZ71.58, GZ71.59, GZ71.60, GZ71.61, GZ71.62, GZ71.63, GZ71.64, GZ71.65, GZ71.66, GZ71.67, GZ71.68, GZ71.69, GZ71.70, GZ71.71, GZ71.72, GZ71.73, GZ71.74,GZ71.75, GZ71.76, GZ71.77, GZ71.78, GZ71.79, GZ71.80, GZ71.81, GZ71.83, GZ71.84, GZ71.85, GZ71.86, GZ71.87, GZ71.88, GZ71.89, GZ71.90, GZ71.91, GZ71.92, GZ71.93

Muhteşem Gökhan Yücel
Head of Notified Body

21 April 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-18-535, Revision Number: 02

Concerned medical devices;

Product: Pipelines and Stations for Medical Gases
Model: GZ71.01, GZ71.02, GZ71.03, GZ71.04, GZ71.05, GZ71.06, GZ71.07, GZ71.08, GZ71.09, GZ71.10, GZ71.11, GZ71.12, GZ71.13, GZ71.14, GZ71.15, GZ71.16, GZ71.17, GZ71.18

Product: Pipelines and Stations for Vacuum
Model: VK40.02, VK40.03, VK40.04, VK40.05, VK40.06, VK40.07, VK40.08, VK40.09, VK40.10, VK40.11, VK40.12, VK40.13, VK40.14, VK40.15

Product: Anaesthetic Gas Scavenging (AGSS) System
Model: VK50.01, VK50.02, VK50.03, VK50.04

Product: Pendant Unit
Model: FX40.05, FX40.10, FX40.15, FX40.20, FX40.25

Product: Patient Bed Head Unit
Model: GB22.10, GB22.20, GB22.30, GB22.40, GB22.01, GB22.02, GB22.03, GB22.04

Product: Anaesthetic Gas Scavenging Terminal Unit and Probe
Model: PR80.26, PR80.27, PR80.28, PR80.29, PR80.30, PR80.31, JK91.20, JK91.21, JK91.22, JK91.23, JK91.24, JK91.25, JK91.26, JK91.27, JK91.28

Muhteşem Gökhan Yücel
Head of Notified Body

21 April 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-18-535, Revision Number: 02

Concerned medical devices;

Product: Jacks and Outlet for Compressed Medical Gas
Model: JK90.50, JK90.51, JK90.52, JK90.53, JK90.54, JK90.55, JK90.56, JK90.57, JK90.58, JK90.70, JK90.71, JK90.72, JK90.73, JK90.74, JK90.75, JK90.76, JK90.77, JK90.78, JK90.80, JK90.81, JK90.82, JK90.83, JK90.84, JK90.85, JK90.86, JK90.87, JK90.88, JK90.90, JK90.91, JK90.92, JK90.93, JK90.94, JK90.95, JK90.96, JK90.97, JK90.98, JK91.10, JK91.11, JK91.12, JK91.13, JK91.14, JK91.15, JK91.16, JK91.17, JK91.18, PR80.01, PR80.03, PR80.04, PR80.05, PR80.06, PR80.08, PR80.09, PR80.10, PR80.11, PR80.13, PR80.14, PR80.15, PR80.16, PR80.18, PR80.19, PR80.20, PR80.21, PR80.23, PR80.24, PR80.25, PR82.01, PR82.03, PR82.04, PR82.05, PR82.06, PR82.08, PR82.09, PR82.10, PR82.11, PR82.13, PR82.14, PR82.15, PR82.16, PR82.18, PR82.19, PR82.20, PR82.21, PR82.23, PR82.24, PR82.25

Product: Jacks and Outlet for Vacuum
Model: PR80.02, PR80.07, PR80.12, PR80.17, PR80.22, PR82.02, PR82.07, PR82.12, PR82,17, PR82.22, JK90.60, JK90.61, JK90.62, JK90.63, JK90.64, JK90.65, JK90.66, JK90.67, JK90.68

Product: Manifold and Line Pressure Regulators
Model: GZ71.20, GZ71.21, GZ71.22, GZ71.23, GZ70.10, GZ70.20, GZ70.30, GZ70.40, GZ70.50

Product: Pressure Regulator
Model: FG50.10, FG50.20, FG50.40, FG50.50, FG50.11, FG50.21, FG50.41, FG50.51, FG50.12, FG50.22, FG50.42, FG50.52, FG50.13, FG50.23, FG50.43, FG50.53, FG50.14, FG50.24, FG50.44, FG50.54, FG50.15, FG50.25, FG50.45, FG50.55, FG50.16, FG50.26, FG50.46, FG50.56

Muhteşem Gökhan Yücel
Head of Notified Body

21 April 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-18-535, Revision Number: 02

Concerned medical devices;

Product: Pressure Regulator with Flowmeter
Model: FM21.85, FM21.86, FM21.87, FM21.88

Product: Vacuum Regulators
Model: FG50.30, FG50.31, FG50.32, FG50.33, FG50.34, FG50.35, FG50.36, FG51.01, FG51.02, FG51.03, FG51.04, FG51.05, FG51.06, FG51.07, FG52.01, FG52.02, FG52.03, FG52.04, FG52.05, FG52.06, FG52.10, FG52.11, FG52.12, FG52.13, FG52.14, FG52.15, FG53.01, FG53.02, FG53.03, FG53.04, FG53.05, FG53.06, FG53.10, FG53.11, FG53.12, FG53.13, FG53.14, FG53.15

Product: Surgical Suction Unit
Model: SU60, SU60.10, SU60.15, SU60.22, SU60.33, SU60.05

Product: Central Vacuum System
Model: AT20.75

Product: Electrosurgical Unit
Model: NS01.60, NS02.00 Touch, NS02.50, NS04.00

Product: Medical Copper Tubings

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

21 April 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

kiwa

İNSPİTAL MEDİKAL TEKNOLOJİ ANONİM ŞİRKETİ

KARAOĞLAN MAHALLESİ KÜME EVLERİ NO: 745 GÖLBAŞI - ANKARA - TURKEY

with a scope of

DESIGN, DEVELOPMENT, PRODUCTION, INSTALLATION, DISTRIBUTION AND SERVICES OF OPERATION THEATER EQUIPMENTS, INTENSIVE CARE UNIT AND EMERGENCY, MEDICAL SERVICE EQUIPMENTS, PATIENT ROOM AND CLINICAL EQUIPMENTS, STERILIZATION AND STAINLESS STEEL EQUIPMENTS, MEDICAL GAS SYSTEM AND EQUIPMENTS, SUCTION ACCESSORIES, HOSPITAL, AMBULANCE AND LABORATORY EQUIPMENT CONCEPTIONS

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.5.5" "7.5.7" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 11038
Initial Certification Date	: 02 August 2018
Certification Date	: 21 March 2019
Expiration Date	: 01 August 2021

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-955A-A5FF

Last Modified: 21 March 2019 - R 01

AT UYGUNLUK BEYANI
EC Declaration of Conformity

Bu ürünlerin MDD 93-42 EEC yönetmeliğinin son yayınlanan gereksinimlerine göre üretilip kontrol edildiğini "inspital" markasına ait olarak tamamen kendi sorumluluğumuz altında olduğunu beyan ederiz. / *We declare that, these products which belong to "inspital" brand are completely under our responsibility also producted and checked according to the requirements of latest revision of MDD 93-42 ECC.*

Üretici firma / *Manufacturer:*	İNSPİTAL MEDİKAL TEKNOLOJİ A.Ş.
Adres /*Address:*	Karaoğlan Mah. Küme Evleri No:745 06830 Gölbaşı / Ankara, TÜRKIYE
Tel / *Phone :*	+90 312 619 02 22
Faks / *Fax:*	+90 312 619 02 25
Web / E-Mail:	www.inspital.com / info@inspital.com
Ürün Adı / *Product Name:*	Ameliyat Lambası / *Operating Lamp*
Ürün markası /:	İNSPİTAL
Ürün Modeli /*Product Model:*	**LD10.01 , LD10.02 , LD10.03, LD20.24 , LD20.52 , LD20.53**
Uygulanan Standartlar *Applicable Harmonized Standards:*	TS EN 13485.2016, TS EN 60601-1:2009 /A1:2014, TS EN 60601-1-2:2016, TS EN 60601-1-6:2010, TS EN 60601-1-8:2008, TS EN 60601-2-41, TS EN ISO 14155-2012,TS EN 55011 :2016, TS EN 62304:2009, TS 3033 EN 60529, IEC 60417:2002, TS EN 50419:2006, TS EN ISO 780:2016, TS ISO 129-1:2012, TS EN ISO 15223-1: 2016, 2011/65/EU:2013, TS EN ISO 10993-1:2011, TS EN ISO 14971: 2013, TS EN 62366-1:2015.
Uygunluk Değerlendirme Yolu Conformity Asssesment Route	**MDD (93/42/EEC) EK VII** MDD (93/42/EEC) ANNEX VII
Ürün Sınıfı Class of Product	**EK 9, KURAL 12'ye göre Sınıf I** Annex 9, Rule 12, Class I
GMDN Kodu / *GMDN Code:*	12282
Onaylanmış Kuruluş Numarası: *Number of Notified Body:*	1984
Sertifika Numarası: *Certificate Number:*	M11038
Sertifika Başlangıç Tarihi : *Initial Date of Certificate:*	02.08.2018
Sertifika Bitiş Tarihi: *Certificate Valid Until:*	01.08.2021
Yer ve yayın tarihi: *Place and date of issue:*	02 Ağustos 2018, İstanbul, Türkiye

CE

Kalite Yönetim Temsilcisi /
Quality Representative
Yeşim SEKİZELMA

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Üzümcü Tıbbi Cihaz Ve Medikal Gaz Sistemleri San. ve Tic. A.Ş.
Company Address	: Oğulbey Mah. Kumludere Cad. No:1/1A Gölbaşı ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Medical Gas System and Electrosurgical Products - Class IIb, IIa
GMDN	: 10217, 42549, 36271, 35630, 36810, 37512, 34849, 47860, 47860, 43438, 44809, 15615, 36778, 35030, 11067

Product Types are attached.

Certificate Number	: M.2019.106.12408
Report Number	: MD.3754.IB
Initial Assessment Date	: 28.05.2019
Registration Date	: 09.08.2019
Revision Date /No	: 26.08.2020/02
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive 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 audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

This document containing 3 (three) pages is the Annex of the Certificate with the revision number 02, with the number M.2019.106.12408 and with the registration date of 09.08.2019 and with the revision date of 26.08.2020 issued for "Üzümcü Tıbbi Cihaz Ve Medikal Gaz Sistemleri San. ve Tic. A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Medical Gas Systems					
Flowmeter - Class IIb GMDN: 42549					
Models					
1200.05	1200.10	1200.15	1200.25	1200.30	1200.00B
1200.00N	1200.00E	1200.05U	1200.10U	1200.15U	1274.00
1200.20U	1220.05	1220.10	1220.15	1220.20	1222.05
1230.05	1230.10	1230.15	1270.00	1273.00	
Bed Head Units and Pendants **Bed Head Units – Class IIb GMDN: 36271**					
1000.10	1000.60	1030.10	1035.20	1035.75	1040.30
1000.20	1000.70	1030.20	1035.30	1040.09	1045.10
1000.30	1000.85	1030.30	1035.55	1040.10	1045.20
1000.50	1000.95	1035.10	1035.65	1040.20	1065.10
1065.11	1065.13	1065.15	1065.30	1070.30	
1065.12	1065.14	1065.20	1068.10	1070.50	
Bed Head Units and Pendants **Pendants - Sınıf IIb GMDN: 35630,36810**					
5070.30	5070.50	5070.65	5070.75L	5070.81	1085.80
5070.40	5070.60	5070.75	5070.80	5075.45	1085.90
5070.45	5070.61	5070.76	5070.80L	5075.50	
Medical Gas Terminal Units / Medical Gas Outlets and Probes / Medical Gas Outlets - Class IIb GMDN: 36271					
Models					
1001.05	1001.59	1003.59	1004.58	1005.52	1001.05
1001.50	1003.50	1004.05	1004.59	1005.58	1001.50
1001.51	1003.51	1004.50	1005.05	1005.59	1001.51
1001.52	1003.52	1004.51	1005.50	1008.51	1001.52
1001.58	1003.58	1004.52	1005.51		1001.58
Medical Gas Terminal Units / Medical Gas Outlets and Probes / Vacuum Outlets - Class IIb GMDN: 37512					
Models					
1002.05	1002.51	1002.58	1002.50	1002.52	1002.59
Medical Gas Terminal Units / Medical Gas Outlets and Probes / AGSS - Anaesthetic Gas Scavenging Outlets and Probes **- Class IIb GMDN: 34849**					
Models					
1007.05	1007.10	1017.10	1607.05	1607.10	2027.10

Medical Gas Terminal Units / Medical Gas Outlets and Probes / Probes for Compressed Medical Gases **- Class IIb GMDN: 36271**					
Models					
1601.05	1603.10	1604.15	1241.05	1243.10	1245.15
1601.10	1603.15	1605.05	1241.10	1243.15	1246.05
1601.15	1604.05	1605.10	1241.15	1245.05	1246.10
1603.05	1604.10	1605.15	1243.05	1245.10	1246.15
Medical Gas Terminal Units / Medical Gas Outlets and Probes / Probes for Vacuum **- Class IIb GMDN: 37512**					
Models					
1602.05	1602.15	1242.10	1244.05	1244.15	
1602.10	1242.05	1242.15	1244.10		

UDEM APPROVED 2292

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

This document containing 3 (three) pages is the Annex of the Certificate with the revision number 02, with the number M.2019.106.12408 and with the registration date of 09.08.2019 and with the revision date of 26.08.2020 issued for "Üzümcü Tıbbi Cihaz Ve Medikal Gaz Sistemleri San. ve Tic. A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

Regulators for Use with Medical Gases / Pressure Regulators for Terminal Units (OTC included) - Class IIb GMDN: 47860				
Models				
1401.05	1403.05	1404.05	1405.05	OTC-50
1401.10	1403.10	1404.10	1405.10	OTC-51
1401.15	1403.15	1404.15	1405.15	OTC-52
1401.05	1403.05	1404.05	1405.05	OTC-50

Regulators for Use with Medical Gases / High Pressure Reducers - Class IIb GMDN: 47860			
Models			
4000.10	4000.15	4000.30	4000.80
4000.10A	4000.15A	4000.30A	4000.80A

Regulators for Use with Medical Gases / Regulators for Use with Cylinders - Class IIb GMDN: 43438		
Models		
OBR-50	OBR-51	OBR-80

Regulators for Use with Medical Gases / Regulators for Use with Terminal Units - Class IIb GMDN: 44809					
Models					
1402.05	1402.10R	1422.10	1520.00D		
1402.10	1402.15R	1422.15	1420.20D		
1402.15	1420.20N	1422.20	1420.20B		
1402.05R	1422.05	1520.00B	1520.00N		

Pipelines and Stations for Medical Gases / Area Gas Control Boxes- Class IIb GMDN: 36271					
Models					
956280601	956280603	956280901	956280903	956281201	956281203
956281501	956281503	956280302	956280304	956280602	956280604
956280902	956280904	956281202	956281204	956281502	956281504
956280301	956280303				

Pipelines and Stations for Medical Gases / Oxygen Station- Class IIb GMDN: 36271				
Models				
MOS-4M	MOS-10	MOS-16	MOS-30	MTO-2
MOS-6	MOS-11	MOS-20	MOS-40	

Pipelines and Stations for Medical Gases / Nitrous Oxide Station- Class IIb GMDN: 36271				
Models				
MAS-4M	MAS-10	MAS-16	MAS-30	MTA-2
MAS-6	MAS-11	MAS-20	MAS-40	

Pipelines and Stations for Vacuum / Vacuum Station (Vertical)- Class IIb GMDN: 15615		
Models		
VRD-42	VRD-102	VRD-202
VRT-43	VRT-103	VRT-203

Pipelines and Stations for Vacuum / Vacuum Station (Horizantal)- Class IIb GMDN: 15615		
Models		
VYD-42	VYD-102	VYD-202
VYT-43	VYT-103	VYT-203

Pipelines and Stations for Vacuum / Vacuum Station (Mini)- Class IIb GMDN: 15615
Models
VPY-70

Central Vacuum Trolley- Class IIa GMDN: 36778
Models

UDEM APPROVED 2292

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

This document containing 3 (three) pages is the Annex of the Certificate with the revision number 02, with the number M.2019.106.12408 and with the registration date of 09.08.2019 and with the revision date of 26.08.2020 issued for "Üzümcü Tıbbi Cihaz Ve Medikal Gaz Sistemleri San. ve Tic. A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

30400	30402	30403	30405
Electrosurgical Units			
Electrosurgical Cautery- Class IIb GMDN: 35030			
Models			
EK-160	EK-250	EK-410	
Cryotheraphy Device - Class IIa GMDN: 11067			
Models			
KRY-10	KRY-10S		
Surgical Suctions Mobile Series – Class IIa GMDN: 10217			
Models			
Amb	PA-1R	PA-2	PA-2S
Surgical Suctions Novela Series – Class IIa GMDN: 10217			
Models			
Novela	Novela Extractor	Vela	

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ

SERTİFİKA
CERTIFICATE

TS EN ISO 13485:2016 Tıbbi Cihazlar Kalite Yönetim Sistemi
Medical Devices Quality Management System as per TS EN ISO 13485:2016

In accordance with BBS procedures, it is hereby certified that

ÜZÜMCÜ

ÜZÜMCÜ TIBBİ CİHAZ VE MEDİKAL GAZ SİSTEMLERİ SAN. VE TİC. A.Ş.

Oğulbey Mahallesi 3058 Cadde No:2 Gölbaşı / ANKARA / 06830

BBS prosedürlerine göre yukarıda belirtilen standart şartlarını karşıladığını kanıtlamıştır.
Applies a management system in line with the above standard for the following scope

Kapsam

Ameliyathane ekipmanları, yoğun bakım ve acil servis ekipmanları, hasta odası ve klinik ekipmanları, sterilizasyon ve paslanmaz çelik ekipmanları, medikal gaz sistemi ve ekipmanları, hastane, ambulans ve laboratuvarların ekipmanlarının tasarımı, geliştirilmesi, üretimi, montajı, dağıtımı ve servisi.

Scope

Operating room equipment, intensive care and emergency service equipment, patient room and clinical equipment, sterilization and stainless-steel equipment, medical gas system and equipment, hospital, design of ambulance and laboratories equipment, development, manufacture, assembly, distribution and service of equipment.

Sertifika No / *Ceritificate No* 1256-01

İlk Belge Tarihi / *Initial Certification* 28.04.2022
Belge Geçerlilik Tarihi / *Valid Until* 27.04.2025

Belgelendirme Kuruluşu / *Certification Body*
BBS A.Ş.

Ankara, 28.04.2022

Belgelendirme BBS tetkik ve belgelendirme prosedürlerine uygun olarak gerçekleşmiştir ve düzenli gözetim tetkiklerine tabidir.
Certification was conducted in accordance with BBS auditing and certification procedures and is subject to regular surveillance audits.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

TÜRKAK
Medikal Cihazlar
TS EN ISO 13485: 2016
AB-0021-YS

TÜRKAK BDS NO
YS-2505-590C

Bu sertifikanın geçerlilik durumu www.bbsas.com.tr ve tbds.turkak.org.tr adreslerinden doğrulanabilir.
Belge üzerindeki karekod QR okuyucu ile okutulmak suretiyle de doğrulama yapılabilir.
The authenticity of this certificate may be verified at www.bbsas.com.tr and tbds.turkak.org.tr.
The authenticity may also be checked with the QR Code above.

BBS BELGELENDİRME EĞİTİM VE GÖZETİM HİZMETLERİ A.Ş.
Cevizlidere Mah. 1246 Sokak No: 4/20 P.K. 06520 ÇANKAYA / ANKARA / TÜRKİYE
www.bbsas.com.tr

CERTIFICATE

Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2020-05-06
Valid until	2021-10-14		
Previous expiry date			

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Management of design and manufacturing, trade, packaging and assistance of: medical devices (DM), in vitro-diagnostic medical devices (IVD), accessories

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) Italia

SGQ N° 007A

CERTIFICATO CE

Certificato n. 1951/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

3A HEALTH CARE S.r.l.

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

mantiene nello stabilimento di:

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Apparecchi per aerosolterapia

Accessori per apparecchi per aerosolterapia

Aspiratori

Aspiratori per ambulanza

Modd. come da documento 'Allegato al Certificato CE no. 1951/MDD - Elenco dei Dispositivi' rev. 2 del 2021/05/06; tale allegato costituisce parte integrante e sostanziale del presente certificato.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

DM17-0016835-01; DM18-0024812-01; DM18-0029038; DM18-0034026-01; DM19-0036397-01; DM19-0038533-01; DM20-0048704-01; DM20-0051712-01; DM20-0055254-01; DM20-0058652-01; DM20-0059928-01; DM21-0063468-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2017-11-18
Data aggiornamento:	2021-05-06
Sostituisce:	2021-02-23
Data scadenza:	2024-05-26

IMQ

EC CERTIFICATE

Certificate No 1951/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

3A HEALTH CARE S.r.l.

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

manages in the factory of:

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Aerosoltherapy equipment

Accessories for aerosoltherapy equipment

Suction equipment

Suction equipment for ambulance

Type ref. as to document 'Annex of EC Certificate no. 1951/MDD - Device List' rev. 2 dated 2021/05/06; this annex is integral and substantial part of this certificate.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM17-0016835-01; DM18-0024812-01; DM18-0029038; DM18-0034026-01; DM19-0036397-01; DM19-0038533-01; DM20-0048704-01; DM20-0051712-01; DM20-0055254-01; DM20-0058652-01; DM20-0059928-01; DM21-0063468-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2017-11-18
Updated:	2021-05-06
Substitution Date:	2021-02-23
Expiry Date:	2024-05-26

IMQ

DocuSign

Allegato al Certificato CE n. 1951/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1951/MDD - Device List

rev. 2 del/of **2021/05/06**

Categoria di dispositivo: Device category:	**Apparecchi per aerosolterapia** Aerosoltherapy equipment
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**HAPPYNEB II ;** **HAPPYNEB III ;** **AIRJOLIE 2 DELUXE ;** **HOSPYNEB professional ;** **COMP-A NEB ;** **ATOMIZER ;** **RESPIRO ;** **ISINEB ;** **NEBBY ;** **NEBBY PLUS ;** **SPEEDY ;** **PICONEB ;** **FUN-NEB ;** **MIDINEB ;** **MIKRONEB ;** **MYNEB ;** **TURBONEB** **3A HEALTH CARE S.r.l.**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**AEROSAN +** **Messer Medical**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**JC-117 ;** **JC-118 ;** **JC-118G ;** **JC-1301;** **JC-117P** **Joycare**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**m213A** **Medicura**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**Salus 54901** **Olimpic**

Allegato al Certificato CE n. 1951/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1951/MDD - Device List

rev. 2 del/of **2021/05/06**

Categoria di dispositivo: Device category:	**Apparecchi per aerosolterapia** Aerosoltherapy equipment
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**DOCTORNEB** **Imetec**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**AIROFAMILY MAX** **Airssential Home**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**Beper 40.110** **Beper**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**SANITY Inhalator PRO** **Sanity**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**TARTU' ;** **Arya ;** **Kosmo** **Prontex**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**LTK150 - NYXY ;** **LTK160 - NYXY FAMILY ;** **LTK170 - NYXY PRO ;** **LT139 - Hospyneb professional** **Moretti**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**Inhalator Amineb 2** **PMT**

Allegato al Certificato CE n. 1951/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1951/MDD - Device List

rev. 2 del/of **2021/05/06**

Categoria di dispositivo: Device category:	**Apparecchi per aerosolterapia** Aerosoltherapy equipment
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**NIVEC III** **MGE**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**ECONEB** **Trister**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**Air 100** **Colpharma**

Allegato al Certificato CE n. 1951/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1951/MDD - Device List

rev. 2 del/of **2021/05/06**

Categoria di dispositivo: Device category:	**Accessori per apparecchi per Aerosolterapia** Accessories for aerosoltherapy equipment
Modello/i: Model(s):	**Forcella nasale (NEB103) ;** **Tubo di collegamento (NEB104) ;** **Mascherina adulto (NEB105) ;** **Mascherina pediatrica (NEB106) ;** **Boccaglio (NEB202);** **Ampolla FASTERJET (NEB101) ;** **Kit accessori FASTERJET (NEB100) ;** **Boccaglio con valvola (NEB102);** **Kit accessori FASTERJET (NEB120) ;** **Kit accessori FASTERJET (NEB130);** **Kit accessori FASTERJET (NEB140);** **Kit accessori FASTERJET per TURBONEB (NEB141) ;** **Kit accessori FASTERJET (NEB150);** **Kit accessori FASTERJET (NEB160);** **Ampolla NEBJET con connettore (NEB201);** **Kit accessori NEBJET (NEB200);** **Kit accessori NEBJET (NEB220) ;** **Kit accessori NEBJET (NEB230);** **Kit accessori NEBJET (NEB240);** **Kit accessori NEBJET (NEB250) ;** **Kit accessori NEBJET (NEB260) ;** **Ampolla TECHNOJET (NEB1000) ;** **Kit accessori TECHNOJET (NEB1002) ;** **Ampolla QUICKJET con connettore (NEB3001) ;** **Kit accessori QUICKJET (NEB3000) ;** **NASALJET (NEB5000);** **NASALJET basic**
Marca/Marche: Trade mark(s):	**3A HEALTH CARE S.r.l.**
Modello/i: Model(s):	**Kit accessori ADAPTAIR N300K2 (NEB1001) ;** **Kit accessori NEBJET (NEB270) ;** **Doccia micronizzata Corman N100D (NEB5001)**
Marca/Marche: Trade mark(s):	**Corman**
Modello/i: Model(s):	**kit accessori NEBJET c/mascherina pediatrica (NEB214) ;** **kit accessori NEBJET c/mascherina adulto (NEB215) ;** **Ampolla NEBJET (NEB217)**
Marca/Marche: Trade mark(s):	**PMT**

Allegato al Certificato CE n. 1951/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1951/MDD - Device List

rev. 2 del/of **2021/05/06**

Categoria di dispositivo: Device category:	**Accessori per apparecchi per Aerosolterapia** Accessories for aerosoltherapy equipment
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**NASALJET - LTK185 (NEB5009) ;** **Ampolla FASTERJET - LTR140 (NEB129) ;** **Ampolla NEBJET - LTR141 (NEB225)** **Moretti**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**Rapid Mask - kit completo per aerosolterapia (NEB248) ;** **Rapid Ampolla nebulizzatrice con raccordo e curva (NEB249) ;** **RHINO CARE** **Prontex**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**Kit accessori NEBJET (NEB226)** **Messer Medical**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**Kit ampolla NEBJET +nasale+boccaglio+filtri (NEB219) ;** **Kit accessori NEBJET+filtri (NEB241)** **Rosner**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**SANITY Nosalek JET (NEB5007) ;** **Kit accessori Sanity Inhalator Pro (NEB1028) ;** **Ampolla Sanity Inhalator Pro (NEB1029)** **Sanity**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**Ampolla NEBJET 5317 - BN3050 (NEB239) ;** **Raccordo snodabile 5317 - BN3070 (NEB242) ;** **Kit nasale/boccaglio 5317 - BN3040 (NEB243) ;** **Maschera adulto 5317-BN3030 (NEB244) ;** **Tubo aria 1 mt 5317-BN3020 (NEB245) ;** **Mascherina regol. GWM 5317-BN3010 (NEB246)** **Imetec**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**Doccia nasale LAICA ANE052 (NEB5010)** **Laica**

Allegato al Certificato CE n. 1951/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1951/MDD - Device List

rev. 2 del/of **2021/05/06**

Categoria di dispositivo: Device category:	**Aspiratori** Suction Equipment
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**ASPEED PROFESSIONAL - 1 POMPA;** **ASPEED PROFESSIONAL - 2 POMPE;** **ASPEED 3.0; ASPEED 2 - 1 POMPA;** **ASPEED 2 - 2 POMPE; MINIASPEED BATTERY PLUS;** **MINIASPEED BATTERY PRO;** **MINIASPEED BATTERY EVO;** **MAXIASPEED 6.2;** **MAXIASPEED 6.2P;** **MAXIASPEED 6.4;** **MAXIASPEED 6.4P;** **MAXIASPEED 9.2;** **MAXIASPEED 9.2P;** **MAXIASPEED 9.4;** **MAXIASPEED 9.4P** **3A HEALTH CARE S.r.l.**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**SAM HOSPY 2 POMPE;** **SAM 420 LX** **MGE**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**Promedic SP-00 ;** **Promedic SP-01** **Trimpeks**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**VORTECO AS-100 EMERGENCY** **Alsa**
Modello/i: Model(s): **Marca/Marche:** Trade mark(s):	**IREDEEM MINIASPEED BATTERY EVO** **Iredeem**

Allegato al Certificato CE n. 1951/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1951/MDD - Device List

rev. 2 del/of **2021/05/06**

Categoria di dispositivo: Device category:	**Aspiratori** Suction Equipment
Modello/i: Model(s):	**ASPIMED 1.8 - LTA410;** **ASPIMED 1.8 - LTA415;** **ASPIMED 1.9 - LTA420;** **ASPIMED 4.1;** **ASPIMED 4.2**
Marca/Marche: Trade mark(s):	**Moretti**

Allegato al Certificato CE n. 1951/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 1951/MDD - Device List

rev. 2 del/of **2021/05/06**

Categoria di dispositivo: Device category:	**Aspiratori per ambulanza** Suction equipment for ambulance
Modello/i: Model(s):	**MINIASPEED BATTERY EVO PLUS**
Marca/Marche: Trade mark(s):	**3A HEALTH CARE S.r.l.**
Modello/i: Model(s):	**IREDEEM MINIASPEED BATTERY EVO PLUS**
Marca/Marche: Trade mark(s):	**Iredeem**

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
CERT-16906-2006-AQ-IND-SINCERT

Initial certification date:
04 January 2006

Valid:
16 December 2020 – 15 December 2023

This is to certify that the management system of

Moretti S.p.A.

Via Bruxelles, 3 - Loc. Meleto - 52022 CAVRIGLIA (AR) - Italy

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design, production and management of the production, distribution and placing on the market of durable medical equipment in the rehabilitation and home healthcare and devices for patient positioning and transport. Marketing and distribution of general non-active, non-implantable medical devices and Devices for wound care (sterile and non-sterile), Monitoring devices, Device for home care, Active rehabilitation devices

Place and date:
Vimercate (MB), 23 December 2020

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 003 A
SGA N° 003 D
SGE N° 007 M
SCR N° 004 F
EMAS N° 009 P
PRD N° 003 B
PRS N° 094 C
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento SGQ, SGA, PRD, PRS, ISP, GHG, LAB e LAT, di MLA IAF per gli schemi di accreditamento SGQ, SGA, SSI, FSM e PRD e di MRA ILAC per gli schemi di accreditamento LAB, MED, LAT e ISP

For the issuing office:
DNV GL - Business Assurance
Via Energy Park, 14, - 20871 Vimercate (MB) - Italy

Zeno Beltrami
Management Representative