PO 45

beurer medical

PO 45 Pulsoximeter

german engineering

SpO_2 and Pulse

Ermittlung der Sauerstoffsättigung (SpO_2), der Herzfrequenz (Puls) und des Perfusions Index (PI)

- Ermittlung der arteriellen Sauerstoffsättigung (SpO_2), der Herzfrequenz (Pulsfrequenz) und des Perfusions Index (PI)
- Sehr einfache und vollkommen schmerzfreie Messung
- Klein und leicht für zu Hause und unterwegs
- Besonders geeignet für Personen mit:
  - Herzinsuffizienz
  - Chronisch obstruktiven Lungenerkrankungen
  - Asthma bronchiale
- Anwendbar bei Sport in großen Höhen (z.B. Bergsteigen, Skifahren und Sportfliegerei)
- Symbolanzeige bei unruhiger Messung
- Leicht ablesbares Farbdisplay
- Farbdisplay mit 7 Anzeigenformaten
- Einstellbare Display-Helligkeit
- Graphische Pulsanzeige
- Batteriewechselanzeige
- Abschaltautomatik
- Inkl. Halteband und Gürtel-Tasche
- Medizinprodukt
- Inkl. 2 x AAA Batterie
- Produktmaße: 59 x 33 x 34 mm
- Produktgewicht: ca. 31,5 g (ohne Batterien)
- 5 Jahre Garantie
- PZN: 16743306
- VE: 4 / Transportkarton: 8 x 4
- EAN-Nr.: 4211125 45434 0
- Art.-Nr.: 454.34

Digitally signed by Dicusar Vladimir
Date: 2022.12.07 13:34:48 EET
Reason: MoldSign Signature
Location: Moldova

beurer health and well-being	Title	EC Declaration of Conformity
	File	BM 85_EC DoC_Beurer_20200623

Manufacturer:	Beurer GmbH (see address in footer)
Product category:	Blood Pressure Monitor
Product type:	BM 85

The product specified above is in conformity with the provisions of the following Union legislation and harmonized standards.

93/42/EEC	Medical device directive (MDD)
UMDNS code and name:	16-174 Blood Pressure Monitor, electronic, manual
Classification/applied rule(s):	Class IIa/rule 10
Conformity assessment procedure:	Annex II - excluding section 4

The notified body mdc medical device certification GmbH, located at Kriegerstr. 6, 70191 Stuttgart, Germany, identification number 0483, issued in the course of the mentioned conformity assessment procedure the following certificate:

Certificate no. and validity:	D1311700043, valid to 2024-05-26
	EN 60601-1:2006 + A1:2013 IEC 60601-1-2:2014 IEC 80601-2-30:2009 EN 1060-1:1995 + A2:2009 EN 1060-3:1997 + A2:2009 ISO 81060-2:2013

2014/53/EU	Radio equipment directive (RED)
	EN 62479:2010 EN 301 489-1 V2.2.0 (2017-03) EN 301 489-17 V3.2.0 (2017-03) EN 300 328 V2.1.1 (2016-11)
2011/65/EU	Restrictions of the use of certain hazardous substances in electrical and electronic equipment (ROHS)

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of:	Beurer GmbH
Place, date of issue:	Ulm, 23.06.2020
Name, function, signature, stamp:	Daniel Kämmerer, Team Leader RA Beurer GmbH Söflinger Straße 218 • 89077 Ulm

GVS Filter Technology UK – Legal Manufacturer
Medical Air Filtration Division
NFC House
Vickers Industrial Estate
Mellishaw Lane
LA3 3EN

Tel: +44 (0) 1524 847600
www.gvs.com

E C Declaration of Conformity

We declare that the undernoted Class IIa Medical Devices are in conformity with the essential requirements and provisions of EC Directive 93/42/EEC and following changes (2007/47/EEC), Annex V Harmonised Standards.

Device Description
Products as per attached product schedule.

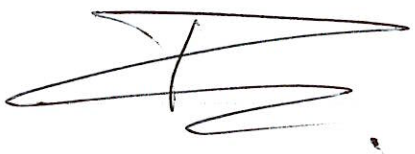
Directives:
Medical Devices Directive 93/42/EEC via the route of Annex V, products are Class IIa, UK Statutory Instrument SI 618 2002 and other applicable standards and regulatory requirements listed in Section 7 of the GVS Filter Technology – Medical Air Filtration Division technical data file.

Certificate number 690080 issued by BSI Group, The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands with Notified Body Number 2797.

EU Authorised Representative: GVS S.p.A, Via Roma 50, 40069 Zola Predosa, Bologna, Italy.

This Declaration of conformity is issued under the sole responsibility of the legal manufacturer.

Signed by



Paulo Raquel
GVS UK Managing Director

Date: 25/05/21

Product Schedule

Category 1 – HME Devices for anaesthesia, respiratory and critical care/HMEF filters for anaesthesia Respiratory and critical care

4244/03	ECO MAXI Pleat
4244/711	MAXI HME Pleat
4244/712	MAXI HME Pleat Without Port
4244/761	Eco-therm HEPA filter with coil paper HME
4331/01	ECO HMEF
4331/01DFK	Eco HMEF With Connectors
4331/01DGK	Eco HMEF With Connectors
4331/50	ECO Maxi HME
4333/01	Eco HMEF
4333/01BNK	Eco HMEF and elbow
4333/01DBK	Eco HMEF + tube + connectors
4333/01DEK	Eco HMEF + tube + connectors
4333/01DDK	Eco HMEF + tube + connectors
4333/01DFK	HMEF, Luer Lid with Expandable Tube
4333/01DGK	Eco HMEF with connectors
4333/50	ECO Maxi Straight HME
4333/710	MAXI Angled HMEF
4333/711	MAXI Straight HMEF
4333/712	MAXI Straight HMEF
4333/712BNK	MAXI Straight HMEF + elbow
4333/714	ECO Maxi Angled HMEF
4333/721	Eco Range HMEF (white foam)
4333/750	MAXI Angled HME
4333/751	MAXI HME
4333/752	ECO Maxi HME
4333/754	ECO Maxi Angled HME
4333/760	Eco MAXI angled coil paper HMEF
4333/761	Eco MAXI straight coil paper HMEF
4333/770	Eco MAXI angled coil paper HME
4333/771	Eco MAXI straight coil paper HME
4333/772	Eco MAXI straight coil paper HME
8866/50	Comfort fit HME
8866/100	Comfort fit HMEF
8866/100DEK	Comfort fit HMEF + tube + connectors
9064/711	MIDI HMEF
9064/711BNK	MIDI HMEF + elbow
9064/751	MIDI HME
9064/761	Eco MIDI straight coil paper HMEF

9065/710	MIDI Angled HMEF
9065/750	MIDI Angled HME
9065/760	Eco MIDI angled coil paper HMEF
9065/770	Eco MIDI angled coil paper HME
9066/711	MINI HMEF
9066/751	MINI HME
9066/761	Eco MINI straight coil paper HMEF
9067/710	MINI Angled HMEF
9067/750	MINI Angled HME
9067/760	Eco MINI angled coil paper HMEF
9080/100	Neo-natal HMEF
9080/100BNK	Neo Natal HMEF with elbow
9080/710	MICRO MINI angled HMEF
9080/750	MICRO angled HME
9085/751	MICRO Lo-Volume HME
9085/771	ECO Micro Lo-Volume coil paper HME
9500/01	Tracheal HME
9500/03	Tracheal Blue HME
9500/04	Tracheal HME
9500/710	Micro tracheal
9500/750	Micro Tracheal
A540	Elbow with sampling port
A541	Elbow without sampling port
A542	Double Swivel Elbow
A543	Double Swivel Elbow
A620/40/61	Expandable Tubing with Gas Sampling Elbow
A620/41/61	Expandable Tubing with Elbow
A620/42/61	Expandable Tubing with Double Swivel Elbow and Port
A620/43/61	Expandable Tubing with Double Swivel Elbow
A620/60/61	Attachment

Category 2 – Electrostatic filters and attachments for anaesthesia, respiratory and critical care/Pleated mechanical filters and attachments for anaesthesia, respiratory and critical care.

1200/08	Medipleat Autoclavable Filter
1200/20	Medipleat Autoclavable Filter
1210/09	Autoclavable Filter
1420/01	Medguard
1420/03	Medguard
1420/03BOK	Medguard + Connector
2800/01	Spiroguard
2800/01BFK	Spiroguard with Nose Clip
2800/01BMK	Spiroguard with Bite Grip
2800/01DAK	Spiroguard with Nose Clip and Bite Grip
2800/01DHK	Spiroguard with Bite Grip, Mouthpiece, Nose Clip
2800/01DJK	Spiroguard with Mouthpiece and Nose Clip
2800/02	Spiroguard
2800/02BFK	Spiroguard with Nose Clip
2800/02BWK	Spiroguard with Mouthpiece
2800/02DAK	Spiroguard with Nose Clip and Bite Grip
2800/03	

2800/03BFK	Spiroguard with Nose Clip
2800/03DAK	Spiroguard with Nose Clip and Bite Grip
2800/03DJK	Spiroguard with Mouthpiece and Nose Clip
2800/10	Spiroguard
2800/10DAK	Spiroguard with Nose Clip and Bite Grip
2800/21	Spiroguard Integral Mouthpiece
2800/21BFK	Spiroguard Integral Mouthpiece with Nose Clip
2800/22	Spiroguard
2800/22BFK	Spiroguard with Nose Clip
2800/22DAK	Spiroguard with Nose Clip and Bite Grip
2800/23	Spiroguard with Integral mouthpiece side
2800/24	Spiroguard
2800/25	Spiroguard with Integral mouthpiece
2800/26	Spiroguard
2800/27	Spiroguard with Integral Mouthpiece
2800/30	Spiroguard Integral Mouthpiece
2800/31	Spiroguard Integral Mouthpiece
2800/31BFK	Spiroguard Integral Mouthpiece with Nose Clip
2800/32	Spiroguard
2800/728	Compact Electrostatic Spirometry Filter
2800/729	Compact Electrostatic Spirometry Filter
2800/R1	Spiroguard Re-usable
2800/R2	Spiroguard Re-usable
2800/R3	Spiroguard Re-usable
2802/01	Spiroguard Adaptor
2802/02	Spiroguard Adaptor
2802/03	Spiroguard Adaptor
2802/04	Spiroguard Adaptor
2802/05	Spiroguard Adaptor
2802/06	Spiroguard Adaptor
2802/07	Spiroguard Adaptor
2802/08	Spiroguard Adaptor
2802/09	Spiroguard Adaptor
2802/10	Spiroguard Adaptor
2802/11	Spiroguard Adaptor
2802/12	Spiroguard Adaptor
2802/13	Spiroguard Adaptor
2802/14	Spiroguard Adaptor
2802/15	Spiroguard Adaptor
2802/16	Spiroguard Adaptor
2802/17	Spiroguard Adaptor
2802/18	Spiroguard Adaptor
2802/19	Spiroguard Adaptor
2802/20	Spiroguard Adaptor
2802/21	Spiroguard Adaptor
2802/22	Spiroguard Adaptor
2802/23	Spiroguard Adaptor
2802/24	Spiroguard Adaptor
2802/25	Spiroguard Adaptor
2802/26	Spiroguard Adaptor

2802/27	Spiroguard Adaptor
2802/28	Spiroguard Adaptor
2802/29	Spiroguard Adaptor
2802/30	Spiroguard Adaptor
2802/31	Spiroguard Adaptor
2802/32	Spiroguard Adaptor
3000/03	Multi-vent
3000/04	Multi-vent tapered
3000/07	Multi-vent
3000/11	Multi-vent flat top
3000/12	Multi-vent flat top
3000/740	Expiratory Filter
4020/01	ECO Machine Filter
4020/03	Single Walled Machine Filter
4020/06	ECO Machine Filter
4020/10	Machine Filter
4220/01	Eco maxipleat
4220/04	ECO Filter
4222/01	ECO slimline
4222/01BWK	Eco slimline and mouthpiece
4222/01DFK	Eco slimline, Luer Lid + Expandable Tube
4222/01DDK	Eco slimline+tube+connectors
4222/02	ECO slimline
4222/02BWK	Eco slimline and mouthpiece
4222/03	ECO slimline
4222/700	MAXI Maxi Angled Filter
4222/701	Eco Maxi Filter
4222/702	MAXI Maxi Filter
4222/703	MAXI Maxi Filter
4244/01	Eco maxi-pleat
4244/01DBK	Pleated filter and collapsible tube
4244/01DEK	Maxi Pleat with connectors
4244/02	ECO Maxi Pleat
4244/04	ECO maxi-pleat
4244/06	ECO maxi-pleat
4244/700	MAXI Maxi Angled Pleat
4244/701	Eco Maxi Pleat
4244/702	MAXI Maxi Pleat
4444/01	Slimline Bacterial/Viral
4444/01BWK	Slimline Electrostatic with mouthpiece
4444/06	Slimline Electrostatic with Integral Mouthpiece
4444/66	Ultra-High Efficiency Slimline
6888/01	Maxi pleat/2
6888/20	Maxi pleat
6888/21	Maxi Pleat ULPA Filter
8444/01	Maxi pleat/1
8444/27	Maxi pleat
8866/01	Comfort fit bacterial/viral
9066/701	MINI Filter
9066/701BNK	MINI Filter + elbow

9067/700	MINI Angled Filter
9080/01	Neo-natal/Bacterial/Viral
9080/700	MICRO Angled Filter
A539	Bitegrip Mouthpiece
A571	Mouthpiece

Category 3 – Activated Carbon and Smoke Evacuation Filters.

2200/47	Smoke Filter
2200/47BBK	Smoke Set
2200/47BDK	Smoke Set
2200/947	90mm Smoke Evacuation Filter

Category 4 – Vent, Suction, Insufflation and Irrigation

2000/01	Vent filter
2000/02	Vent Filter - Autoclavable
2000/05	Vent Filter
2000/05BAK	Vent Filter Set
2000/05DLK	Vent Filter Set
2000/05DTK	Vent Set
2000/05DUK	Vent Set
2000/05DWK	Vent Set
2000/05DXK	Vent Set
2000/06	Vent Filter
2000/07	Vent Filter - Autoclavable
2000/08	Vent Filter
2000/09	Vent Filter
2000/12	Vent Filter
2000/16	Vent Filter
2000/17	Vent Filter
2000/18	Vent filter
2000/18BEK	Vent Set
2000/20	Vent Filter
2000/22	Transducer filter
2000/31	Vent Filter
2000/35	Vent filter
2000/37	Vent filter
2000/38	Vent filter
2000/39	Vent Filter
2000/42	Vent Filter
2000/53	Suction Filter
2200/01	Insufflation Filter
2200/01BCK	Insufflation Set
2200/01DKK	Insufflation Set
2200/02	Suction Filter
2200/02DIK	Suction Set
2200/05	Insufflation Filter
2200/05BRK	Insufflation Set

2200/06	Suction Filter
2200/15	Insufflation Filter
2200/16	Suction Filter
2200/21	Suction Filter
2200/25BUK	Insufflation Set
2200/25DSK	Insufflation Set
2200/26	Suction Filter
2200/33	Insufflation Filter
2200/35	Suction Filter
2200/36	Suction Filter
2200/48	Insufflation filter
2200/48BIK	Insufflation Set
2200/55	Suction Filter
2200/56	Insufflation Filter
2200/62BHK	Insufflation Set
2200/65	Insufflation filter
2200/70	Suction Filter
2200/902	90MM Suction Filter
2200/911	90MM Suction Filter
6421/04	Insufflation Filter
6421/04BGK	Hi Flow Insufflation Kit
6421/04DVK	Insufflation Set

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

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 067329 0010 Rev. 01

Manufacturer:

Wenzhou Kangju Medical Instrument Co., Ltd.
81 Liuzhai Luodong South Street, Yongzhong
325000 Wenzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

Aneroid Sphygmomanometer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH1852011

Valid from: 2018-12-17
Valid until: 2023-10-01

Date, 2018-12-17

Stefan Preiß

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®

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

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 067329 0010 Rev. 01

Facility(ies):

Wenzhou Kangju Medical Instrument Co., Ltd.
81 Liuzhai Luodong South Street, Yongzhong, 325000 Wenzhou,
Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Nanjing Kangju Medical Instrument Co.,Ltd.
27 Huashan Road Gaochun Economy Zone, 211300 Nanjing,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Production Quality Assurance
No. 19 0248 QS/NB

The quality system of manufacturer

Wuxi Medical Instrument Factory Co., Ltd.

No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City, Jiangsu 214194 China

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

for the following product category(ies):

Mercury free clinical thermometer

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. The Notified Body has audited this system with limitation to those aspects of manufacture concerned with the conformity of the devices with metrological requirements. This part of quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance.

Valid from: 2021-03-23
Valid until: 2024-05-21
First Issued: 2019-05-22
Revision: a

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-03-23

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0248 QS/NB

issued for manufacturer:

Wuxi Medical Instrument Factory Co., Ltd.
No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City,
Jiangsu 214194 China

Product(s):

Name:	**Mercury free clinical thermometer**
Trade name(s):	AIESI; APTEO; EUROSIREL; EVOLU; FarmaMed; FLAEM; GIMA; ia; Lamotherm; Med+s; Sanitec; Tecnico; UNIFAMILY
Model(s):	CR.W00
Class:	Im
GMDN:	34343

Facility(ies):

Wuxi Medical Instrument Factory Co., Ltd.

No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City, Jiangsu 214194 China

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-03-23
Revision: a

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0248 QS/NB

issued for manufacturer:

Wuxi Medical Instrument Factory Co., Ltd.
No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City,
Jiangsu 214194 China

Certificate History:

Revision	Date	Reference Number	Action
	2019-05-22	803602800	Certification
a	2021-03-23	803602897	Adding new brand names

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-03-23
Revision: a

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

piuma up3

Prevenzione del decubito

fino al III stadio

Compressore fissabile al letto

Connettore veloce e tappo funzione trasporto

Funzioni

ALTERNATO

STATICO

Allarmi

Visivi e sonori

BASSA PRESSIONE

Cod. **LAD470** Kit materasso Nylon® + PVC, compressore e coperta Nylon® + PU
Cod. **LAD471** Kit materasso Nylon® + TPU, compressore e coperta Nylon® + PU
OPTIONAL Cod. **LAR702** Coperta bielastica, antimicrobica, impermeabile, traspirante e verificata secondo le norme europee di reazione al fuoco

	L:	P:	H:	
Materasso	196 cm	86 cm	13 cm	160 Kg
Compressore	30 cm	13,5 cm	11 cm	-

piuma up3

Prevenzione del decubito

fino al IV stadio

Compressore fissabile al letto

Connettore veloce e tappo funzione trasporto

Funzioni

ALTERNATO

STATICO

Allarmi

Visivi e sonori

BASSA PRESSIONE

Cod. **LAD475** Kit materasso Nylon® + PVC, compressore e coperta Nylon® + PU
Cod. **LAD476** Kit materasso Nylon® + TPU, compressore e coperta Nylon® + PU
OPTIONAL Cod. **LAR703** Coperta bielastica, antimicrobica, impermeabile, traspirante e verificata secondo le norme europee di reazione al fuoco

	L:	P:	H:	
Materasso	200 cm	86 cm	20,3 cm	200 Kg
Compressore	30 cm	13,5 cm	11 cm	-

piuma up4

Prevenzione del decubito

fino al IV stadio

Compressore fissabile al letto

Connettore veloce e tappo funzione trasporto

Funzioni

TEMPO DI CICLO

ALTERNATO

STATICO

MAX FIRM

SEAT INFLATE

Allarmi

Visivi e sonori

BASSA PRESSIONE

MANCANZA CORRENTE

ASSISTENZA TECNICA

Cod. **LAD480** Kit materasso Nylon® + PVC, compressore e coperta Nylon® + PU
Cod. **LAD481** Kit materasso Nylon® + TPU, compressore e coperta Nylon® + PU
OPTIONAL Cod. **LAR703** Coperta bielastica, antimicrobica, impermeabile, traspirante e verificata secondo le norme europee di reazione al fuoco

	L:	P:	H:	
Materasso	200 cm	86 cm	20,3 cm	200 Kg
Compressore	30 cm	13,5 cm	11 cm	-

piuma up4

Prevenzione del decubito

fino al IV stadio

Compressore fissabile al letto

Connettore veloce e tappo funzione trasporto

Funzioni

TEMPO DI CICLO

ALTERNATO

STATICO

MAX FIRM

SEAT INFLATE

Allarmi

Visivi e sonori

BASSA PRESSIONE

MANCANZA CORRENTE

ASSISTENZA TECNICA

Cod. **LAD491** Kit materasso Nylon® + TPU, compressore e coperta Nylon® + PU
OPTIONAL Cod. **LAR705** Coperta bielastica, antimicrobica, impermeabile, traspirante e verificata secondo le norme europee di reazione al fuoco

	L:	P:	H:	
Materasso	208 cm	86 cm	20,3 cm	200 Kg
Compressore	30 cm	13,5 cm	11 cm	-

Serie piuma up

Sistemi antidecubito

per terapie domiciliari e a lungo termine

LEVITAS®

piuma up

La cura e la prevenzione delle piaghe da decubito

La cura e la prevenzione delle lesioni da decubito prevede iter specifici, con cure locali e sistemiche da valutare caso per caso, in termini generali è opportuno prevedere sia il ricorso a manovre di frequente mobilizzazione del paziente che l'utilizzo, costante, di ausili volti a ridurre e ridistribuire la pressione di appoggio.

E proprio con la finalità di rispondere con specificità alle esigenze di prevenzione di tutti coloro che, per malattia, anzianità o decorso postoperatorio, sono costretti ad uno stato di immobilità, Moretti Spa ha aggiornato ed ampliato la propria linea Piuma Up di Levitas.

Il marchio "Piuma Up" firma oggi una gamma ampia, aggiornata e specializzata di materassi ad aria con compressore, grazie ai quali predisporre una soluzione antidecubito dinamica, per pazienti con lesioni da decubito fino al IV stadio.

La linea Piuma Up di Levitas by Moretti Spa

La linea si propone di rispondere con specificità anche alle casistiche più problematiche e complesse e si compone di sette diversi kit composti da materasso, compressore e coperta coprimaterasso (solo Piuma Up 3 e 4).

La gamma "Piuma Up" offre quattro diverse soluzioni:

Piuma Up e Piuma Up 1
per i livelli di decubito al **I stadio**

Piuma Up 2
per i livelli di decubito fino al **II stadio**

Piuma Up 3 e Piuma Up 4
per i livelli di decubito fino al **IV stadio**

piuma up

Prevenzione del decubito
fino al I stadio

Funzione

ALTERNATO

Cod. **LAD462** Kit materasso a bolle e compressore Piuma Up

	L:	P:	H:	
Materasso	200 cm	90 cm	7,6 cm	135 Kg
Compressore	27 cm	13 cm	10,5 cm	-

piuma up1

Prevenzione del decubito
fino al I stadio

Funzione

ALTERNATO

Cod. **LAD464** Kit materasso a bolle e compressore Piuma Up 1
OPTIONAL Cod. **LAR306** Coperta standard in PU

	L:	P:	H:	
Materasso	200 cm	90 cm	15,2 cm	145 Kg
Compressore	27 cm	13 cm	10,5 cm	-

piuma up2

Prevenzione del decubito
fino al II stadio

Funzione

ALTERNATO

Cod. **LAD463** Kit materasso in Nylon® + PVC e compressore Piuma Up 2
OPTIONAL Cod. **LAR304** Coperta standard in PU
OPTIONAL Cod. **LAR305** Coperta bielastica

	L:	P:	H:	
Materasso	200 cm	86 cm	10,2 cm* 12 cm**	145 Kg
Compressore	27 cm	13 cm	10,5 cm	-

*solo elemento **inclusa base di supporto

I vers. - 02-2021 - Moretti Service&Consulting

Série piuma up

DISTRIBUITI DA

MORETTI® Innovazione al servizio del cliente

www.morettispa.com

Seguici su

Conformi al nuovo regolamento MDR 2017/745 EU

MORETTI

MORETTI S.p.A.
Via Bruxelles, 3 - Meleto
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www.morettispa.com
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Part. IVA 00306090515
Meccanografico AR 005370
Reg. Imp. Arezzo 00306090515

R.E.A. Arezzo 68869
Cap. Soc. € 1.500.000,00
C/C Postale 13682521

DICHIARAZIONE DI CONFORMITA'

CE

Ai sensi del Regolamento UE 2017/745

MORETTI S.p.A.

SRN: *IT-MF-000005980*

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

MATERASSI ANTIDECUBITO PIUMA UP

UDI-DI di Base: *805287964201706QY*

Sono conformi alle disposizioni applicabili del

Regolamento 2017/745 sui DISPOSITIVI MEDICI
del 5 aprile 2017

Ed ai seguenti standard internazionali

EN ISO 14971:2012 – EN ISO 15223-1:2017 – EN 60601-1:2006 – EN 60601-1-2:2007

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

1. I dispositivi in oggetto soddisfano i requisiti generali di sicurezza e prestazione così come richiesti dall'allegato I del regolamento 2017/745 come prescritto dall'allegato IV del suddetto regolamento.
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 in conformità a quanto stabilito dall'allegato VIII del suddetto regolamento.
7. La MORETTI S.p.A. mantiene e mette a disposizione delle Autorità Competenti, per almeno 10 anni dalla data di fabbricazione dell'ultimo lotto, la documentazione tecnica di cui agli allegati II e III comprovante la conformità al regolamento 2017/745.
   I dispositivi in oggetto sono prodotti utilizzando materiali non pericolosi in conformità alla direttiva RoHS - 2011/65/UE.

Cavriglia, 28/05/2021

MORETTI S.p.A.
FILIPPO FABBRINI
Amministratore delegato

Allegati:
Allegato A – Elenco dispositivi medici
Allegato B – Elenco codici UDI-UDI

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DECLARATION OF CONFORMITY

CE

Regulation EU 2017/745

MORETTI S.p.A.

SRN: *IT-MF-000005980*

declares under its sole responsibility that the product made and traded by Moretti S.p.A.
and belonging to the group of

ALTERNATING MATTRESS AND PUMP PIUMA UP

Basic UDI-DI: *805287964201706QY*

complies with the

Regulation 2017/745 on MEDICAL DEVICES
of 5 April 2017

and the following international standards

EN ISO 14971:2012 – EN ISO 15223-1:2017 – EN 60601-1:2006 – EN 60601-1-2:2007

For this purpose, Moretti S.p.A. guarantees and declares under its sole responsibility what follows:

1. The devices satisfy the requirements of general safety and performance requested by the Annex I of regulation 2017/745 as laid down by the Annex IV of the above mentioned regulation.
2. The complete list of this range of medical devices is indicated in Annex I
3. The devices *ARE NOT MEASURING INSTRUMENTS*.
4. The devices *ARE NOT MADE FOR CLINICAL TESTS*.
5. The devices are packed in *NON-STERILE BOX*.
6. The devices belong to class I in accordance with the provisions of Annex VIII of the above mentioned regulation
7. Moretti S.p.A. provides to the Competent Authorities the technical documentation set out in Annexes II and III to prove the conformity to the 2017/745 regulation, for at least 10 years from the last lot production
8. The devices are produced using not dangerous materials in conformity with directive RoHS 2011/65/UE

Cavriglia, 28/05/2021

MORETTI S.p.A.
FILIPPO FABBRINI
CEO

Annexes:
Annex A – Medical devices list
Annex B – UDI-DI codes list

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DECLARACIÓN DE CONFORMIDAD

CE

Según el Reglamento UE 2017/745

MORETTI S.p.A.

SRN: *IT-MF-000005980*

declara bajo su exclusiva responsabilidad que los productos fabricados y puestos en comercio por la misma MORETTI S.p.A. y que hacen parte de la familia

COLCHÓN ANTIESCARAS Y COMPRESOR DE AIRE ALTERNANTE

UDI-DI* básico*: *805287964201706QY*

cumplen con las disposiciones aplicables del:

Reglamento 2017/745 sobre los
PRODUCTOS SANITARIOS del 5 abril 2017

Y a los siguientes estándares internacionales

EN ISO 14971:2012 – EN ISO 15223-1:2017 – EN 60601-1:2006 – EN 60601-1-2:2007

Por eso, MORETTI S.p.A. garantiza y declara bajo su propia exclusiva responsabilidad lo que sigue:

1. Los productos en cuestión satisfacen los requisitos generales de seguridad y prestación como requerido por el anexo 1 del mismo reglamento 2017/745 como prescrito por el anexo IV del mismo reglamento.
2. La lista completa de los productos en objeto está indicada en el anexo A de esa declaración.
3. Los productos en cuestión NO SON INSTRUMENTOS DE MEDICIÓN.
4. Los productos en cuestión NO ESTÁN DESTINADOS A INVESTIGACIONES CLÍNICAS.
5. Los productos en cuestión se comercializan en presentación NO ESTÉRIL.
6. Los productos en cuestión deben considerarse de clase I en conformidad a lo establecido en el anexo VIII del mismo reglamento.
7. MORETTI S.p.A. mantiene y pone a disposición de las Autoridades Competentes, por 10 años desde la fecha de fabricación del ultimo lote, la documentación técnica especificada en los anexos II y III que comprueba la conformidad con el mismo reglamento 2017/45.
8. Los dispositivos se fabrican con materiales no peligrosos de conformidad con la Directiva RoHS - 2011/65 / EU

Cavriglia, 28/05/2021

MORETTI S.p.A.
FILIPPO FABBRINI
Director General

Anexos:
Anexo A – Lista productos sanitarios
Anexo B – Lista código UDI-DI

ALLEGATO / ANNEX / ANEXO - A
ELENCO DISPOSITIVI MEDICI / MEDICAL DEVICES LIST / LISTA PRODUCTOS SANITARIOS

Famiglia: **MATERASSI ANTIDECUBITO PIUMA UP**
Group: **ALTERNATING MATTRESS AND PUMP PIUMA UP**
Familia: **COLCHÓN ANTIESCARAS Y COMPRESOR DE AIRE ALTERNANTE PIUMA UP**

Codice - Code Código	Descrizione	Description	Descripción
LAD462	Materasso con compressore PIUMA UP a bolle con regolazione	Bubble mattress and pump PIUMA UP with regulation	Colchón de burbujas y compresor PIUMA UP con regulación
LAD463	Materasso con compressore PIUMA UP ad elementi trasversali	Bubble mattress and pump PIUMA UP with transversal cells	Colchón de burbujas y compresor PIUMA UP con celdas transversales
LAD464	Materasso con compressore PIUMA UP a bolle doppio con regolazione	Double bubble mattress and pump PIUMA UP with regulation	Colchón de burbujas doble y compresor PIUMA UP con regulación
LAD470	Materasso con compressore PIUMA UP ad elementi trasversali - PVC - 12,7 CM	Bubble mattress and pump PIUMA UP with transversal cells – PVC – 12,7 CM	Colchón de burbujas y compresor PIUMA UP con celdas transversales – PVC -12,7 CM
LAD471	Materasso con compressore PIUMA UP ad elementi trasversali - TPU - 12,7 CM	Bubble mattress and pump PIUMA UP with transversal cells – TPU – 12,7 CM	Colchón de burbujas y compresor PIUMA UP con celdas transversales – TPU -12,7 CM
LAD475	Materasso con compressore PIUMA UP ad elementi trasversali - PVC - 20,3 CM	Bubble mattress and pump PIUMA UP with transversal cells – PVC – 20,3 CM	Colchón de burbujas y compresor PIUMA UP con celdas transversales – PVC -20,3 CM
LAD476	Materasso con compressore PIUMA UP ad elementi trasversali - TPU - 20,3 CM	Bubble mattress and pump PIUMA UP with transversal cells – TPU – 20,3 CM	Colchón de burbujas y compresor PIUMA UP con celdas transversales – TPU-20,3 CM
LAD480	Materasso con compressore PIUMA UP ad elementi trasversali - PVC - 20,3 CM	Bubble mattress and pump PIUMA UP with transversal cells – PVC – 20,3 CM	Colchón de burbujas y compresor PIUMA UP con celdas transversales – PVC -20,3 CM
LAD481	Materasso con compressore PIUMA UP ad elementi trasversali - TPU - 20,3 CM	Bubble mattress and pump PIUMA UP with transversal cells – TPU – 20,3 CM	Colchón de burbujas y compresor PIUMA UP con celdas transversales – TPU-20,3 CM
LAD482	Materasso con compressore PIUMA UP ad elementi trasversali - TPU - 20,3 CM	Bubble mattress and pump PIUMA UP with transversal cells – TPU – 20,3 CM	Colchón de burbujas y compresor PIUMA UP con celdas transversales – TPU-20,3 CM
LAD490	Materasso con compressore PIUMA UP ad elementi trasversali - TPU - 120 CM	Bubble mattress and pump PIUMA UP with transversal cells – TPU – 120 CM	Colchón de burbujas y compresor PIUMA UP con celdas transversales – TPU-120 CM

Cavriglia, 28/05/2021

ALLEGATO / ANNEX / ANEXO - B
ELENCO CODICI UDI-DI / UDI-DI CODES LIST / LISTA CODIGOS UDI-DI

Famiglia: **MATERASSI ANTIDECUBITO PIUMA UP**
Group: **ALTERNATING MATTRESS AND PUMP PIUMA UP**
Familia: **COLCHÓN ANTIESCARAS Y COMPRESOR DE AIRE ALTERNANTE PIUMA UP**

MORETTI Codice / Code / Código	**UDI-DI Codice / Code / Código**
LAD462	08057018714278
LAD463	08057018716845
LAD464	08052879640681
LAD470	08052879642739
LAD471	08052879642746
LAD475	08052879642753
LAD476	08052879642760
LAD480	08052879642777
LAD481	08052879642784
LAD482	08052879642791
LAD490	08052879642807
LAD491	08052879642814

Cavriglia, 28/05/2021

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

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 091264 0006 Rev. 02

Manufacturer:

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,
Pingshan District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Fetal Monitor, Fetal & Maternal Monitor, Ultrasonic Pocket Doppler, Patient Monitor, Electrocardiograph, Central Monitoring System, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, PC ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Diagnostic Ultrasound System, Holter System, Telemetry Transmitter, Anaesthetic Workstation, Ventilator, Biofeedback and Stimulation System, Ambulatory Blood Pressure Monitor, SPO2 Sensor; Temperature Probe; Ultrasonic Transducer.

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.: BJ1989104

Valid from: 2019-11-25
Valid until: 2022-09-17

Date, 2019-11-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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Cap. Soc. € 500.000
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SCHEDA TECNICA DI DISPOSITIVO	Modulo STD Rev. 04 – 31.10.2018

LTD82x	Pulsiossimetro palmare DIMED con allarmi e display grafico.

Destinazione d'uso

Dispositivo per la misurazione non invasiva della saturazione di ossigeno nel sangue e del battito cardiaco.

Caratteristiche principali

Pulsiossimetro di grande affidabilità e precisione, leggero, compatto e idoneo per il monitoraggio di adulti, bambini e neonati. Display LCD ad alta risoluzione. Operazioni con pulsanti brevi e concise, disegnato con impugnatura anatomica antiscivolo, può fornire informazioni continue ed affidabili sulla saturazione di ossigeno. Particolarmente adatto ad ogni Clinica Specializzata, Ospedale e per il trasferimento dei pazienti o per l'assistenza domiciliare. Possibilità di visualizzare il TREND (andamento) in modo GRAFICO ed in modalità TABELLA degli ultimi 10 minuti su un'unica schermata. 300 ore di memoria per 100 pazienti diversi. Possibilità di collegamento al computer con software dedicato opzionale

Immagine prodotto

RIFERIMENTI FABBRICANTE	
Fabbricante ai sensi 93/42	*EDAN INSTRUMENTS INC*
Paese di produzione	*CINA*
Codice produttore	*H100B*
Classe di dispositivo 93/42	*Classe IIa*
Codice di classificazione GMDN	*45607*
Codice di classificazione CND	*Z1203020408*
MATERIALI A CONTATTO CON IL PAZIENTE	
Interno sensore	*Silicone*
DATI TECNICI	
Formato del display	*LCD 128x 64 dot*
Display saturazione SPO2	*0 – 100%*
Display pulsazioni cardiache	*30-254 Bpm*
Alimentazione	*4 pile AA da 1,5V o Alimentatore esterno da 6V*
Durata	*48 h*
Precisione di misurazione SPO2	*+/- 2%*
Precisione di misurazione BPM	*+/- 2 Bpm*
Precisione di misurazione temperatura	*+/- 0,1 ° (solo LTD823)*
Memoria	*100 Pazienti – 300 Ore*
Dimensioni	*160 x 70 x37 mm*
Peso	*165g (senza batterie)*
VARIANTI	
LTD822 – Sensore compatibile BCI	**LTD823 – Sensore e modulo interno NELLCOR**

By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 97750**

Issued To: **Advanced Medical Solutions Ltd**
Premier Park
33 Road One
Winsford Industrial Estate
Winsford
Cheshire
CW7 3RT
United Kingdom

In respect of:

Silver Alginate II Antimicrobial Wound Dressing with Silver Sodium Hydrogen Zirconium Phosphate.

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2006-02-28** Date: **2020-03-27** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01699**

Issued To: **Advanced Medical Solutions Ltd**
Premier Park
33 Road One
Winsford Industrial Estate
Winsford
Cheshire
CW7 3RT
United Kingdom

In respect of:

The design, development and manufacture of sterile medicated and non-medicated alginate/CMC blended wound dressings, alginate wound dressings, CMC wound dressings, polyurethane foam wound dressings, hydrocolloid wound dressings, amorphous hydrogel, membrane wound dressings and silicone wound contact layer.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1997-09-03** Date: **2020-05-18** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 01699

Issued To:

Advanced Medical Solutions Ltd
Premier Park
33 Road One
Winsford Industrial Estate
Winsford
Cheshire
CW7 3RT
United Kingdom

Number	Device Name	Intended Purpose per IFU
Class III		
---	Silver Alginate I Antimicrobial Wound Dressing	See CE 70851
---	Silver Alginate IV Antimicrobial Wound Dressing	See CE 608297
---	Silver Alginate II Antimicrobial Wound Dressing	See CE 97750
---	PHMB Antimicrobial Foam Wound Dressing	See CE 600773
Class IIb		
43186	Non-woven dressings	Moderate to heavily exuding chronic and acute wounds. Single use.
44970	Foam Dressings	Moderate to heavily exuding chronic and acute wounds. Single use.
44970	Lite Foam Dressings	Non to lightly exuding chronic and acute wounds. Single use.
47764	Hydrogels	Necrotic and sloughy wounds with low exudates. Single use.
46855	Silicone Wound Contact Layer	Nil to heavily exuding chronic and acute wounds (with an appropriate secondary dressing). Single use.
44970	Bilaminate Membrane Dressings	Light to moderately exuding superficial, acute wounds. Single use.
43186	Hydrocolloid dressings	Light to moderately exuding chronic and acute wounds. Single use.

First Issued: **1997-09-03** Date: **2020-05-18** Expiry Date: **2024-05-26**