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

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 15 06 21697 017

Manufacturer:

EnviteC - Wismar GmbH
Alter Holzhafen 18
23966 Wismar
GERMANY

Facility(ies):

EnviteC - Wismar GmbH
Alter Holzhafen 18, 23966 Wismar, GERMANY

Product Category(ies):

Oxygen Saturation Sensors and Monitors, Sensors and Control Units for Monitoring of Respiratory Parameters and Gas Exchange, Non-invasive Blood Pressure Euipment, Temperature Sensors

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.: 713063594

Valid from: 2015-09-02
Valid until: 2020-09-01

672976

Date, 2015-08-28

Digitally signed by Grabazei Alexandru
Date: 2019.04.28 23:45:56 EEST
Reason: MoldSign Signature
Location: Moldova

Hans-Heiner Jarke

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

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

Product Service

CERTIFICATE

No. Q5 17 12 21697 018

Holder of Certificate: **EnviteC - Wismar GmbH**
Alter Holzhafen 18
23966 Wismar
GERMANY

Facility(ies):
EnviteC - Wismar GmbH
Alter Holzhafen 18, 23966 Wismar, GERMANY

Certification Mark:

Scope of Certificate: **Design and development, production and distribution of sensors and control units for monitoring of vital physiological parameters, sensors and control units for monitoring of respiratory mechanics parameters and gas exchange, measurement devices and sensors for alcohol blood concentration**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: 713119332

Valid from: 2018-02-06
Valid until: 2021-01-30

Date, 2018-02-06

Stefan Preiß

Page 1 of 1

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

TÜV®

DAkkS CRT2 / 10.13

EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

Company Name	: Morton Medikal San. ve Tic. A.Ş.
Company Address	: İTOB O.S.B. Ekrem Demirtaş Cad. No:9 Tekeli Menderes IZMIR / TURKEY
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Non-sterile Anesthesia and Breathing Circuit - Class IIa Sterile Bacterial Filter - Class IIa Sterile Catheter Mouth - Class IIa Sterile Mortonvent Tracheostomy Filter Set - Class IIa Non-sterile Spirometry Filter and Mouth Piece - Class IIa Sterile Inhalation Holding Chamber - Class IIa Non-sterile Humidifier Chamber - Class IIa Sterile Extension Line - Class IIa Sterile Pleural Drainage System - Class IIa Sterile Y Tur Set - Class IIa Sterile Yankauer Suction Set - Class IIa Non-Sterile Disposible Anesthesia Rebreathing Bag - Class IIa Sterile Video Camera Drape - Class Is Sterile Microscope Drape - Class Is
GMDN	: 37704, 37706, 37798, 37597, 35795, 37597, 13680, 60699, 12170, 16621, 10817, 46102, 35917, 37450, 12535, 34877
	Product Types are attached.
Certificate Number	: M.2017.106.8574
Report Number	: MD.3375.IB
Initial Assessment Date	: 30.05.2017
Registration Date	: 23.06.2017
Revision Date /No	: 18.08.2017/02
Expiry Date	: 22.06.2022

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

UDEM 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 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. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. to whom it must be returned upon 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 the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through www.udemltd.com. tr.

CE 2292

Addrres: 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.udemltd.com.tr

EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Heinen + Löwenstein GmbH & Co. KG

Arzbacher Straße 80
56130 Bad Ems
Deutschland

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

für weitere Fertigungsstätten, Niederlassungen: siehe Anlage 2 / *for additional sites: see annex 2*

Medizinprodukte für Anästhesie, Intensivtherapie, Neonatologie, Phototherapie, Homecare, Schlafdiagnostik und Pulmologie

Medical devices for anaesthesia, intensive care, neonatology, phototherapy, homecare, sleep diagnostic systems and pulmonology

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 04 232 960821
Bericht Nr. / *Report No.* 3516 8077

Gültigkeit / *Validity*
von / *from* 2016-01-09
bis / *until* 2019-01-08
Edition 2

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2016-01-08

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Anlage 1, Blatt 1 von 3
Annex 1, page 1 of 3

Reg.-Nr. / *Reg. No.* 04 232 960821

Produkte der Klasse IIa *Products of class IIa*	Typ *Type*	UMDNS
Atemgasanfeuchter / *Humidifier*	System One 60 Befeuchter	12-050
Wärmebett / *Warming bed*	Lifetherm 2000	13-250
CPAP-Beatmungseinheit / *CPAP units*	Phönix 3i Somnia 3i	11-001 11-001
nCPAP-System *nCPAP system*	NeoJet 2000 nCPAP	11-001
Wärmestrahler / *Heat radiator*	Isotherm	17-956
Polygraph	Mini Screen Plus	13-085
Polysomnograph	Mini Screen Pro	17-458

Bericht Nr. / *Report No.* 3516 8077

Gültigkeit / *Validity*
von / *from* 2016-01-09
Edition 3

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2016-01-08

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
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ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 960821

Produkte der Klasse IIb *Products of class IIb*	Typ *Type*	UMDNS
Anästhesiesystem / *Anaesthesia system*	Sinus	10-145
	Sinus TR	10-145
	Leon, Leon Wand, Leon XS	10-145
	Leon plus, Leon plus Wand	10-145
	Leon MRI	10-145
Säuglingsbeatmungsgerät / *Baby Ventilator*	Leoni plus, Leoni plus HFO, Leoni plus CLAC, Leoni plus HFO CLAC	14-361
	Leoni plus transport, Leoni plus HFO transport	14-361
	Leoni mobil, Leoni mobil 2	14-361
	Leoni 2	14-361
	Leoni 2 transport	14-361
Wärmegerät, Strahlung, Säugling, mobil *Warmer, radiant, infant, mobile*	Lifetherm 2002, 2003	13-250

Bericht Nr. / *Report No.* 3516 8077

Gültigkeit / *Validity*
von / *from* 2016-01-09
Edition 3

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Certification body for medical devices

Essen, 2016-01-08

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

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ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 960821

Produkte der Klasse IIb *Products of class IIb*	Typ *Type*	UMDNS
Intensiv Beatmungsgeräte / *Intensiv Care Ventilators*	sonata	17-429
	elisa	17-429
	elisa 600	17-429
	elisa 800, 800 VIT	17-429

Bericht Nr. / *Report No.* 3516 8077

Gültigkeit / *Validity*
von / *from* 2016-01-09
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ANLAGE / *ANNEX*

Anlage 2, Blatt 1 von 2
Annex 2, page 1 of 2

Reg.-Nr. / *Reg. No.* 04 232 960821

Weitere Fertigungsstätte/Niederlassungen
Additional sites

Heinen + Löwenstein Medizin-Elektronik GmbH Arzbacher Straße 80 56130 Bad Ems Deutschland / Germany	Produktion, Vertrieb und Service von Medizinprodukten für Homecare, Schlafdiagnostik und Pulmologie *Manufacturing, distribution and service of medical devices for homecare, sleep diagnostic and pulmology*
Heinen + Löwenstein Nederland B.V. Anthonie Fokkerstraat 2 3772 MR Barneveld Niederlande / Netherlands	Vertrieb und Service von Medizinprodukten für Anästhesie, Intensivtherapie, Phototherapie und Neonatologie *Distribution and service of medical devices for anaesthesia, intensive care, phototherapy and neonatology*
Heinen + Löwenstein Nederland Homecare B.V. Anthonie Fokkerstraat 2 3772 MR Barneveld Niederlande / Netherlands	Vertrieb und Service von Medizinprodukten für Homecare, Schlafdiagnostik, Atemtherapie und Pulmologie *Distribution and service of medical devices for homecare, sleep diagnostic, respiratory therapy and pulmonology*

Bericht Nr. / *Report No.* 3516 8077

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Edition 2

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Essen, 2016-01-08

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ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 232 960821

Weitere Fertigungsstätte/Niederlassungen
Additional sites

Heinen + Löwenstein GmbH Clemens-Holzmeister-Straße 4 1100 Wien Österreich / Austria	Vertrieb und Service von Medizinprodukten für Anästhesie, Intensivtherapie, Neonatologie Phototherapie und Pulmologie *Distribution and service of medical device for anaesthesia, intensive care, neonatology, phototherapy and pulmonology*
Löwenstein Medical Austria GmbH Schumacherstraße 14 5020 Salzburg Österreich / Austria	Vertrieb und Service von Medizinprodukten für Homecare, Schlafdiagnostik, Atemtherapie und Pulmologie *Distribution and service of medical devices for homecare, sleep diagnostic, respiratory therapy and pulmonology*

Bericht Nr. / *Report No.* 3516 8077

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ZLG-BS-236.10.16

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	20
Primo rilascio / First i*ssue date*	2006-10-25	Valido da / *Valid from*	2016-10-24
Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2016-11-07

Certificate

Certificato CE del Sistema di Garanzia della Qualità/ *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

GIMA S.p.A.

sede operativa / Operational Headquarter:
Via Marconi, 1
20060 Gessate, MI - Italia

sede legale
Via Tommaso Grossi, 2
Milano - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*
Bilancia ad uso medicale / *Scales for medical use*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*
Dispositivi per aerosolterapia / *Nebulizer therapy devices*
Dispositivi per la misurazione della saturazione di O2 / *Oxygen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per misurazione / *Measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Elettrocardiografi / *Electrocardiographs*
Sfigmomanometri / *Sphygmomanometers*

Rif. rapporto di audit/ *Ref. audit report:* 19-20-21/09/2016

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* ==

Rif. analisi dossier progettazione/ *Ref. design dossier analysis:* ==

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

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.kiwacermet.it

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1106

Marca / *Brandname:*
GIMA

Modello / *Model:*

Aspiratori e accessori / *aspirators and accessories*

Tipologia / *Medical Devices:*
Bilancia ad uso medicale / *Scales for medical use*

Classe di rischio / *Risk class:*
I m

Codice NANDO / *NANDO codes:*
MD 0104

Marca / *Brandname:*
GIMA

Modello / *Model:*

ASTRA - FAMILY - PEGASO

Tipologia / *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

Classe di rischio / *Risk class:*
I s

Codice NANDO / *NANDO codes:*
MD 7006

Marca / *Brandname:*
GIMA

Modello / *Model:*

Gimabrush

Chief Operating Officer
Giampiero Belcredi

Kiwa Cermet Italia S.p.A.
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40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

Marca / *Brandname:*
GIMA

Modello / *Model:*
Cervical Spoon

Modello / *Model:*
Cervix Brush Plush

Modello / *Model:*
Gima Collector

Modello / *Model:*
Gimabrush Ball

Modello / *Model:*
Kit ORL sterile / *Sterile ENT kit*

Modello / *Model:*
Kit pap test / *Pap smear kit*

Modello / *Model:*
Spatula legno sterile / *Sterile wooden spatula*

Modello / *Model:*
Spatula plastica sterile / *Sterile plastic spatula*

Modello / *Model:*
Speculum perno - mix / *Vaginal Speculum central pin - mix*

Modello / *Model:*
Speculum perno centrale - grande / *Vaginal Speculum central pin- large*

Modello / *Model:*
Speculum perno centrale - medio / *Vaginal Speculum central pin - medium*

Modello / *Model:*
Speculum perno centrale - piccolo / *Vaginal Speculum central pin - small*

Chief Operating Officer
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www.kiwacermet.it

CERMET

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

Marca / *Brandname:*
GIMA

Modello / *Model:*
Speculum tache - mix / *Vaginal Speculum tache - mix*

Modello / *Model:*
Speculum vite centrale - mix / *Vaginal Speculum middle screw - mix*

Modello / *Model:*
Speculum vite laterale - grande / *Vaginal Speculum side screw - large*

Modello / *Model:*
Speculum vite laterale - medio / *Vaginal Speculum side screw - medium*

Modello / *Model:*
Speculum vite laterale - mix / *Vaginal Speculum side screw - mix*

Modello / *Model:*
Speculum vite laterale - piccolo / *Vaginal Speculum side screw - small*

Modello / *Model:*
Swab plastica sterile / *Sterile plastic swab*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 7006

Marca / *Brandname:*
GIMA

Modello / *Model:*
Proctoscopio adulti / *Adult proctoscope*

Modello / *Model:*
Proctoscopio pediatrico / *Pediatric proctoscope*

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
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E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Dispositivi per aerosolterapia / *Nebulizer therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1102

Marca / *Brandname:*
AKOD PHARMA

Modello / *Model:*
AEROSOL A PISTONE

Modello / *Model:*
AEROSOL AD ULTRASUONI

Marca / *Brandname:*
GIMA

Modello / *Model:*
AEROSOL MISTRAL

Modello / *Model:*
AEROSOL A PISTONE

Modello / *Model:*
AEROSOL A PISTONE CORSIA

Modello / *Model:*
AEROSOL A PISTONE EOLO

Modello / *Model:*
AEROSOL AD ULTRASUONI

Kiwa Cermet Italia S.p.A.
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E-mail: info@kiwacermet.it
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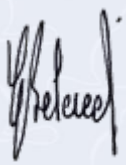
Chief Operating Officer
Giampiero Belcredi



Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della saturazione di O2 / *Oxygen saturation measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
GIMA

Modello / *Model:*

PULSOSSIMETRO / *PULSE OXIMETER*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
ACRAF

Modello / *Model:*

Termometri clinici digitali -Termometro digitale classico Farmamed / *Classic digital Farmamed thermometer*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale Farmamed / *Digital Farmamed thermometer*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale Linea F flessibile / *Digital linea F thermometer flexible*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale NUB Farmamed / *NUB Farmamed Digital thermometer*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale NUB Farmamed Baby / *NUB Farmamed Baby Digital thermometer*

Chief Operating Officer
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CE

Organismo Notificato n. 0476
Notified Body nr. 0476

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.kiwacermet.it

CERMET

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Marca / *Brandname:*
ACRAF

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Farmamed / *Farmamed ecologic thermometer*

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico linea F / *Linea F ecologic thermometer*

Marca / *Brandname:*
CARREFOUR GS

Modello / *Model:*

Termometri clinici digitali -Termometro digitale Carrefour / *Digital Carrefour thermometer*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale GS / *Digital GS thermometer*

Marca / *Brandname:*
CRAF

Modello / *Model:*

Termometri clinici digitali -Termometro digitale classico Linea F / *Classic digital linea F thermometer*

Marca / *Brandname:*
FederFARMA.co

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Profar / *Profar ecologic thermometer*

Marca / *Brandname:*
GABBIANO

Modello / *Model:*

Termometri clinici digitali -Termometro digitale Farmasan / *Farmasan Digital thermometer*

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Farmasan / *Farmasan ecologic thermometer*

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

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www.kiwacermet.it

CERMET

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Marca / *Brandname:*
GIMA

Modello / *Model:*

Termometri clinici digitali -Termometro digitale / *Digital thermometer*

Modello / *Model:*

Termometri clinici digitali -Termometro digitale NUB / *NUB Digital thermometer*

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico / *Ecologic thermometer*

Marca / *Brandname:*
PB PHARMA

Modello / *Model:*

Termometri clinici digitali -Termometro digitale / *Digital GS thermometer*

Marca / *Brandname:*
QUIDNOVI PHARMA

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro ecologico TECNICO Eco / *TECNICO Eco ecologic thermometer*

Marca / *Brandname:*
SSL HEALTHCARE

Modello / *Model:*

Termometri ecologici senza mercurio -Termometro clinico Realcheck mercury free / *Clinical thermometer Realcheck mercury free*

Marca / *Brandname:*
T&B

Modello / *Model:*

Termometri clinici digitali -Termometro digitale 36.2 T&B / *Digital 36.2 T&B thermometer*

Kiwa Cermet Italia S.p.A.
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CERMET

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Dispositivi per misurazione / *Measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
GIMA

Modello / *Model:*

Altimetro - Plicometro - Metro per neonati / *Height meter - Skinfold caliper - Baby measuring meter*

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

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1102

Marca / *Brandname:*
GIMA

Modello / *Model:*

Cannule di Guedel sterili / *Sterile Guedel airways*

Modello / *Model:*

Kit pallone silicone adulti / *Silicone resuscitator kit - adult*

Modello / *Model:*

Maschere laringee riutilizzabili / *Reusable laryngeal mask airways*

Modello / *Model:*

Mascherina per rianimazione CPR / *CPR resuscitator mask*

Modello / *Model:*

Palloni rianimatori / *Resuscitators*

Modello / *Model:*

Accessori -Maschere in silicone autoclavabili / *Silicone autoclavable face masks*

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

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CERMET

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

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

Marca / *Brandname:*
GIMA

Modello / *Model:*

Accessori -Maschere in silicone con cuscinetto e cuffia autoclavabili / *Silicone autoclavable cushion face masks*

Modello / *Model:*

Accessori -Maschere ossigeno / *Oxygen masks*

Modello / *Model:*

Accessori -Mascherine monouso PVC a cuscino d'aria iniettabile / *Disposable PVC injectable air cushion face masks*

Modello / *Model:*

Accessori -Occhiali ossigeno / *Nasal cannula*

Modello / *Model:*

Accessori -Tubo ossigeno / *Oxygen tubing*

Modello / *Model:*

Accessori -Valvola PEEP / *Peep valve*

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

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1403

Marca / *Brandname:*
ACRAF

Modello / *Model:*

Ghiaccio istantaneo monouso Farmamed Gelo Pack / *Farmamed disposable instant ice cold pack*

Kiwa Cermet Italia S.p.A.
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CERMET

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

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

Marca / *Brandname:*
GIMA

Modello / *Model:*

Ghiaccio istantaneo monouso / *disposable instant ice cold pack*

Modello / *Model:*

Ghiaccio istantaneo PE / *PE instant ice cold pack*

Modello / *Model:*

Ghiaccio istantaneo TNT / *TNT instant ice cold pack*

Marca / *Brandname:*
MENARINI

Modello / *Model:*

Ghiaccio istantaneo monouso Menarini / *Menarini disposable instant ice cold pack*

Tipologia / *Medical Devices:*
Elettrocardiografi / *Electrocardiographs*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
GIMA

Modello / *Model:*

ECG PALMARE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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CERMET

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302

Marca / *Brandname:*
ACRAF

Modello / *Model:*
SFIGMO DIGITALE DA POLSO ROSS ANGELINI

Modello / *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO ROSS ANGELINI

Marca / *Brandname:*
AKOD PHARMA

Modello / *Model:*
SFIGMO DIGITALE DA BRACCIO HL AKOD

Modello / *Model:*
SFIGMO DIGITALE DA POLSO HL AKOD

Modello / *Model:*
SFIGMO DIGITALE DA TAVOLO HL AKOD

Marca / *Brandname:*
GIMA

Modello / *Model:*
a mercurio -STAR

Modello / *Model:*
a mercurio -YTON

Modello / *Model:*
a mercurio -YTON PLAUNAZIDE

Modello / *Model:*
Aneroidi -BOSTON

Chief Operating Officer
Giampiero Belcredi

Kiwa Cermet Italia S.p.A.
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Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

Marca / *Brandname:*
GIMA

Modello / *Model:*
Aneroidi -BOSTON COMBISARTAN

Modello / *Model:*
Aneroidi -BOSTON LATEX-FREE

Modello / *Model:*
Aneroidi -BOSTON LOBIVON

Modello / *Model:*
Aneroidi -BOSTON VALPRESSION

Modello / *Model:*
Aneroidi -BOSTON OLPRESS

Modello / *Model:*
Aneroidi -DALLAS

Modello / *Model:*
Aneroidi -GIMATONO

Modello / *Model:*
Aneroidi -LONDON

Modello / *Model:*
Aneroidi -ROMA

Modello / *Model:*
Aneroidi -SIRIO

Modello / *Model:*
Aneroidi -TOKIO

Modello / *Model:*
Aneroidi -TOKIO ZANTIPRESS

Modello / *Model:*
Aneroidi -YTON

Chief Operating Officer
Giampiero Belcredi

CE

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CERMET

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	20
Primo rilascio / First i*ssue date*	2006-10-25	Valido da / *Valid from*	2016-10-24
Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2016-11-07

Certificate

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

Marca / *Brandname:*
GIMA

Modello / *Model:*
digitali -AUTOMATICO DA POLSO

Modello / *Model:*
digitali -24h

Modello / *Model:*
digitali -AMBULATORIALE

Modello / *Model:*
digitali -AUTOMATICO DA BRACCIO

Modello / *Model:*
digitali -DOMINO

Modello / *Model:*
digitali -SENZA MERCURIO

Modello / *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO HL GIMA

Modello / *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO ROSS GIMA

Modello / *Model:*
digitali -SFIGMO DIGITALE DA POLSO HL GIMA

Modello / *Model:*
digitali -SFIGMO DIGITALE DA POLSO ROSS GIMA

Modello / *Model:*
digitali -SFIGMO DIGITALE DA TAVOLO HL GIMA

Modello / *Model:*
digitali -YTON DIGITALE

Chief Operating Officer
Giampiero Belcredi

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia S.p.A.
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Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

Certificate

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	20
Primo rilascio / First i*ssue date*	2006-10-25	Valido da / *Valid from*	2016-10-24
Scadenza / *Valid until*	2021-10-24	Ultima modifica / *Last change date*	2016-11-07

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
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www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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

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:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

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.
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E-mail: info@kiwacermet.it
www.kiwacermet.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
SGA N° 010D
PRD N° 069B
FSM N° 004I
PRS N° 089C

ZERTIFIKAT / *Certificate*

gem. / acc. EN ISO 13485 : 2012 + AC : 2012

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Heinen + Löwenstein GmbH & Co. KG
Arzbacher Straße 80
56130 Bad Ems
Deutschland

mit den Standorten/Gesellschaften gemäß Anlage

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2012 / EN ISO 13485 : 2012 + AC : 2012 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke - eingeführt hat und aufrechterhält. Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2012 / EN ISO 13485 : 2012 + AC : 2012 - Medical devices - Quality management systems - Requirements for regulatory purposes. This certificate is not an authorisation to affix the CE mark.

Geltungsbereich / *Scope*

Entwicklung, Herstellung, Vertrieb und Service von Medizinprodukten für Anästhesie, Intensivtherapie, Neonatologie, Phototherapie, Homecare, Schlafdiagnostik und Pulmologie
Design, manufacturing, distribution and service of medical devices for anaesthesia, intensive care, neonatology, phototherapy, homecare, sleep diagnostic systems and pulmonology

Reg.-Nr. / *Reg.-No.* 04 221 960821
Bericht Nr. / *Report No.* 3516 8076

Gültigkeit / *Validity*
von / *from* 2016-01-09
bis / *until* 2019-01-08
Edition 2

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2016-01-08

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-12007-05-01

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 221 960821

Weitere Fertigungsstätte/Niederlassungen
Additional sites

Heinen + Löwenstein Medizin-Elektronik GmbH Arzbacher Straße 80 56130 Bad Ems Deutschland / Germany	Produktion, Vertrieb und Service von Medizinprodukten für Homecare, Schlafdiagnostik und Pulmologie *Manufacturing, distribution and service of medical devices for homecare, sleep diagnostic and pulmology*
Heinen + Löwenstein Nederland B.V. Anthonie Fokkerstraat 2 3772 MR Barneveld Niederlande / Netherlands	Vertrieb und Service von Medizinprodukten für Anästhesie, Intensivtherapie, Phototherapie und Neonatologie *Distribution and service of medical devices for anaesthesia, intensive care, phototherapy and neonatology*
Heinen + Löwenstein Nederland Homecare B.V. Anthonie Fokkerstraat 2 3772 MR Barneveld Niederlande / Netherlands	Vertrieb und Service von Medizinprodukten für Homecare, Schlafdiagnostik, Atemtherapie und Pulmologie *Distribution and service of medical devices for homecare, sleep diagnostic, respiratory therapy and pulmonology*

Bericht Nr. / *Report No.* 3516 8076

Gültigkeit / *Validity*
von / *from* 2016-01-09
Edition 5

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2016-01-08

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-12007-05-01

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 04 221 960821

Weitere Fertigungsstätte/Niederlassungen
Additional sites

Heinen + Löwenstein GmbH Clemens-Holzmeister-Straße 4 1100 Wien Österreich / Austria	Vertrieb und Service von Medizinprodukten für Anästhesie, Intensivtherapie, Neonatologie Phototherapie und Pulmologie *Distribution and service of medical device for anaesthesia, intensive care, neonatology, phototherapy and pulmonology*
Löwenstein Medical Austria GmbH Schumacherstraße 14 5020 Salzburg Österreich / Austria	Vertrieb und Service von Medizinprodukten für Homecare, Schlafdiagnostik, Atemtherapie und Pulmologie *Distribution and service of medical devices for homecare, sleep diagnostic, respiratory therapy and pulmonology*

Bericht Nr. / *Report No.* 3516 8076

Gültigkeit / *Validity*
von / *from* 2016-01-09
Edition 5

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2016-01-08

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-12007-05-01

EC Certificate

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

Registration No.: HD 60123878 0001

Report No.: 12018179 022

Manufacturer:
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products:
Design and Development, Manufacture of Medical Endoscopy Systems, Diagnostic, Operation and Treatment Products

(see attachments for products and additional sites included)

Replaces Approval, Registration No.: HD 60078827 0001

Expiry Date: 2022-11-02

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: 2017-11-03

Date: 2017-10-12

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜVRheinland

Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60123878 0001
Report No.: 12018179 022

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products included:

Medical Endoscopy Systems:
-Endoscopes
-Endotherapy Devices
-Imaging Processors
-Pumps for Endoscopy
-Light Sources
-Position Detecting Units
-Electrothermal Cautery Units
-Integrated Endosurgery Systems
-Endoscopic Regulation/Control Units
Electrosurgical Equipment
Probes and Transducers for Ultrasonic Lithotriptors
Laparoscopic Insufflators
Ultrasound Surgical Equipment
Disinfecting Units
Capsule Endoscopes and Systems
Ultrasound Diagnostic Imaging Systems

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2017-10-12

M.Sc. M. Aihara

Traducere din limba engleza

TÜVRheinland®

APROBARE

Directiva CE 93/42/CEE Anexa II, excluzând Secţiunea 4
Sistem complet de asigurare a calităţii
Echipamente medicale

Nr. Înregistrare: HD 60123878 0001
Nr. Raport: 12018179 022

Producător: **Olympus Medical Systems Corp.**
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Proiectare şi dezvoltare, producţie de sisteme de endoscopie medicală, produse de diagnostic, operaţie şi tratament.
(a se vedea atasamentele pentru produse si locatii suplimentare incluse)
Înlocuieşte Aprobarea cu nr. de înregistrare: HD 60078827 0001

Data expirarii: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerinţele Anexei II, excluzând secţiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menţionat a stabilit şi aplică un sistem de asigurare a calităţii, care este supus unei supravegheri periodice, definită în Anexa II, secţiunea 5 a directivei menţionate anterior. Pentru comercializarea echipamentelor din clasa III acoperite de acest certificat, este necesar un certificat CE de examinare proiectare în conformitate du Anexa II, secţiunea 4.

Organism notificat
Ştampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Data intrării în vigoare: 03-11-2017

Data. 12.10.2017

TÜVRheinland

Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Certificat
Nr. de inregistrare: HD 60123878 0001
Nr. raport: 12018179 022

Producător: **Olympus Medical Systems Corp.**
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse incluse:
- Sisteme medicale de endoscopie:
  - -Endoscoape
  - -Echipamente endoterapie
  - -Procesoare de imagine
  - -Pompe pentru endoscopie
  - -Surse de lumină
  - -Unităţi de detectare poziţie
  - -Unităţi de cauterizare electrotermică
  - -Sisteme endochirurgicale integrate
  - - Unitati de control/reglare endoscopice
- Echipamente electrochirurgicale
- Sonde şi traductoare pentru litotriptoare cu ultrasunete
- Insuflatoare laparoscopice
- Echipamente chirurgicale cu ultrasunete
- Unitati de sterilizare
- Sisteme şi endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Organism notificat
Ştampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Data: 12.10.2012

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ - FRANCEZĂ
AUT. NR. 22059
TEL.: 0745471452

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60123877 0001

Report No.: 12018179 022

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products: Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Instruments used in conjunction with Endoscopes and Sterile Non Active Instruments used in conjunction with Medical Ultrasound Diagnostic Imaging Systems
Replaces Approval, Registration No.: DD 60116725 0001

Expiry Date: 2022-11-02

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2017-11-03

Date: 2017-10-12

Notified Body

M.Sc. M. Aihara

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.

Traducere din limba engleza

TÜVRheinland

CERTIFICAT CE
Directiva CE 93/42/CEE Anexa V
Asigurarea calităţii producţiei
Echipamente medicale

Nr. Înregistrare: DD 60123877 0001
Nr. Raport: 12018179 022

Producător: **Olympus Medical Systems Corp.**
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Echipamentelor sterile pentru endoterapie, utilizate împreuna cu endoscoape, instrumente sterile non-active utilizate împreună cu endoscoape şi instrumente sterile non-active utilizate împreună cu sisteme medicale de imagistică diagnostic cu ultrasunete.
Înlocuieşte Aprobarea. nr. înregistrare: DD 60116725 0001

Data expirarii: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerinţele Anexei V a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menţionat a stabilit şi aplică un sistem de asigurare a calităţii, care este supus unei supravegheri periodice, definită în Anexa V, secţiunea 4 a directivei menţionate anterior. Pentru comercializarea echipamentelor din clasa IIb şi clasa III acoperite de acest certificat, este necesar un certificat CE de examinare tip în conformitate du Anexa III.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat
Ştampilă:
TÜV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name :	**HK Greatmade Tech LTD**
Manufacturer's Address :	**6th,Building C,PinchuangYuan Science Technology Park, ShuiDou New Village, LongHua Town ,Shenzhen ,China.**
Product :	**Spo2 Sensor, Class I B**
Type Designation/Trademark :	**adult finger clip Sensor**

Product Part No. Of Manufacturer:

AF001-3 ,AF001-1 ,AF001-3D,AF002 .,AF004-3 ,AF005-1 ,AF005-3 ,AF006 ,AF007-1 ,AF007-3 ,AF008-3 ,AF008-1,AF009 ,AF051 ,AF039,AF012 ,AF013-1 ,AF023 ,AF024-1A ,AF024-1B ,AF024-2 ,AF024-3 AF024-1-OXI,AF024-3-OXI,AF024-OXI-GE,AF032-1,AF032-3,AF036,AF037,AF022-3,AF022-1,AF052,A F025,AF026,AF026-3,AF027,AF029,AF028,AF016,AF018,AF017,AF019,AF020,AF021,AF022-1,AF022-3,AF028,AF030,AF031,AF040,AF041,AF043,AF048,AF049,AF050,AF051,AF052,AF056 ,AF057 ,AF058, AF053,AF054,AF056,AF059,AF060,AF061,AF062,AF063,AF064-N/M.AF065,AF066,AF067,AF068,AF06 9,AF070,AF071,AF072,AF073,AF074,AF075,AF076,AF077,AF078,AF079,AF080,AF081,AF082,AF083,A F084,AF085,AF086,AF087,AF088,AF089,AF090,AF091,AF092,AF093,AF094,AF095,AF096,AF097,AF0 98,AF015-3,AF022-1,AF072,AF100,AF100-GE,AF101,AF102,AF103

Authorized representative established within the EU (if applicable):

Company Name :

Company Address :

Person responsible for making this declaration

Name, Surname :	**ZhangHanzhi**
Position/Title :	**Director/ Owner**

Hereby Declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC.

Shenzhen, China

ZhangHanzhi

(Place)

Dec 24th,2012

(Date)

(Company stamp and legal signature)

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name : HK Greatmade Tech Ltd

Manufacturer's Address : 6th floor ,B Building ,ShuiDou New Village , LongHua town .
Shenzhen City , Guang Dong Province , China

Product : Non-Invasive Blood Pressure Cuff and Air Hose

Type Designation/Trademark : N.I.B.P cuff , Class I

Product Part No. Of Manufacturer:
CF001A,CF002A,CF003A,CF004A,CF004LA,CF004TA,CF001B,CF002B,CF003B,CF004B,CF004LB,CF004TB,CF001C,CF002C,CF003C,CF004C,CF004LC,CF004TC,CF001D,CF002D,CF003D,CF004D,CF004LD,CF004TD,CF005,CF005-1.5,CF005N,CF006,CF006N,CF006-,CF007L,CF007B,CF007N,CF008,CF009,CF010,CF011,CF012,CF013,CF014,CF015,CF016,CF017,CF017B,CF018,CF019,CF020,CF021,CF022,CF023-BK,CF023-BK-P,CF023-BL,CF023-BL-P,CF001A-V,CF002A-V,CF003A-V,CF004A-V,CF004LA-V,CF004TA-V,CF001B-V,CF002B-V,CF003B-V,CF004B-V,CF004LB-V,CF04TB-V,
CF1101A/B,CF1102A/B,CF1103A/B,CF1104A/B,CF1105A/B,CF1107A/B,CF1108A/B,CD1109A/B,CF1110A/B,CF1111A/B,CF1112A/B,CF1113A/B,CF1201AB/C/D,CF1202A/B/C/D,CF1203A/B/C/D,CF1204A/B/C/D,CF1205A/B/C/D,CF1207A/B/C/D,CF1208A/B/C/D,CF1209A/B/C/D,CF1210A/B/C/F,CF1211A/B/C/D,CF1212A/B/C/D,CF1213A/B/C/D,CF1501A/B,CF1502A/B,CF1503A/B,CF1504A/B,CF1505A/B,CF1601A/B,CF1602A/B,CF1603A/B,CF1901C,CF1901I,CF1901N,BP04,BP05,BP07,BP09-MF,BP09-MM,BP12,BP15,BP17,BP18,BP20,NIBP-H,NIBP-S,NIBP-Y,NIBP-D.

Authorized representative established within the EU (if applicable):

Company Name :

Company Address :

Person responsible for making this declaration

Name, Surname : ZhangHanzhi

Position/Title : Director , Owner

Hereby we declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC

Shenzhen, China

Zhang Hanzhi

Jan 21th, 2014

(Place) **(Date)**

(Company stamp and legal signature)

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name :	**HK Greatmade Tech Limited**
Manufacturer's Address :	**3th, B Building ,BaifuliIndustrial Zone,Shanghenglang village , LongHua town .**
	Shenzhen City , Guang Dong Province , China
Product :	**Patient Monitor cable and lead, Class I**
Type Designation/Trademark :	**Patient Monitor cable with leadwires**

Product Part No. Of Manufacturer: MC001A-3,MC001B-3, MC001B-5, MC001A-5, MC002A-3, MC002B-3, MC002C-3,MC002D-3, MC003A-5, MC003B-5, MC003C-5, MC003D-5,MC004A-3, MC004B-3, MC005A-5, MC005B-5, MC006A, MC006B, MC007A, MC007B, MC007C, MC007D,MC008, MC009A, MC009B, MC010A,MC010B, MC013-3, MC015-5, MC017A-5, MC017B-5, MC018A-3, MC018B-3,MC019A-3, MC019B-3, MC019C-3,MC019D-3, MC020A-5, MC020B-5, MC020C-5, MC020D-5, MC021A-3,MC021B-3,MC022A-5,MC022B-5,MC023A-3,MC023B-3,MC023C-3,MC023D-3,MC024A-5, MC024B-5,MC024C-5,MC024D-5,MC025A/B/C/D/E/F/G/H-3,MC026A/B/C/D/E/F/G/H-5,MC027-3, MC028-5,MC029A-3,MC029B-3,MC030A-3,MC030B-3,MC031-5,MC032A-5,MC032B-5,MC033A-3, MCD033B-3,MC034A-3,MC034B-3, MC035A-5, MC035B-5,MC036A,MC036B, MC037A-3, MC037B-3, MC038A-5, MC038B-5,MC039-5, MC041A, MC042A-3,MC042B-3, MC043A-5, MC043B-5,MC044-3, MC045.MC046-3,MC046-5,MC047-3,MC047-5 ,MC048-3 ,MC048-5 ,MC049,MC050 ,MC051.MC052A ,MC 052B, MC053-3 ,MC053-5,MC054-3 ,MC054-5,MC055 ,MC056, MC057-4AS,MC057-4IS,MC065-3,MC065-5, MC066,MC067,MC068,MC069-3AS/5AS,MC069-3IG/5IG,

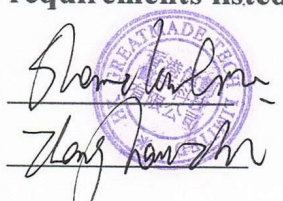
Authorized representative established within the EU (if applicable):

Company Name :	**Prolinx GmbH**
Company Address :	**Brehmstr. 56,40239, Duesseldorf ,Germany**

Person responsible for making this declaration

Name, Surname :	**ZhangHanzhi**
Position/Title :	**Director , Owner**

Hereby we declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC



(Place)
(Company stamp and legal signature)

__Mar 19th ,2018__

(Date)

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name :	**HK Greatmade Tech Limited**
Manufacturer's Address :	**4th, A building ,PinChuangYuan Science Technology Park ,ShuiDou New Village ,LongHua Town Shenzhen City , Guang Dong Province , China**
Product :	**ECG cable and Leadwire, class I**
Type Designation/Trademark :	**ECG cable with leadwires**

Product Part No. Of Manufacturer:
EC001A,EC001AD,EC001B,EC001C,EC001BI,EC001D,EC001DI,EC025A,EC025AD,EC025B,EC025BI,EC025C,EC025D,EC002AD,EC002A,EC002B,EC002BI,EC002C,EC002D,EC027A,EC027B,EC027C,EC027B,EC027A-R,EC027B-R,EC027C-R,EC027D-R,EC028A,EC008B,EC028D,EC028DI,EC030A,EC003AI,EC003A,EC004,EC004B,EC004C,EC005A,EC005B,EC005C,GE-EC022-SA,GE-EC022-CA,EC026A,EC026B,EC026C,EC029A,EC029B,EC024A/B/C/D,EC033A/B/C/D/E,EC038A/B/C/D/E/F,EC040,MR-EC0331A/B/C/D/AD/BI/BI/DI,EC006A/B/C/D,EC007A,EC007B,EC007C,EC007D/E/F/H/G,EC007A-R,EC007B-R,EC007D-R.EC00C-R,EC015A/B/C/D,EC007I,EC009A,EC009B/C/D/E/F,EC021A/B/C/D/E/F,EC010A,EC010B/C/D/E/F,EC016A/B,EC017A/B,EC011A/B/C/D,EC019A/B/C/D,EC020A/B/C/D/E/F/G/H,EC042A/B/C/D,EC041A/I,EC035A/B/C/D/E/F/G/H,EC043A/B,EC012A/B/C,EC012A/B/C/D-HP,EC012E/F,EC013A/B/C/D/E/F/G,EC018A/B/C/D,EC036A/B,EC037A/B,EC039A/B,EC014A/P ,EC023A/B/C,EC034.

Authorized representative established within the EU (if applicable):

Company Name:

Company Address :

Person responsible for making this declaration

Name, Surname : **ZhangHanzhi**

Position/Title : **Director , Owner**

Hereby we declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC

Shenzhen - China

Zhang Hanzhi

___2013.11.01_
(Date)

(Place)
(Company stamp and legal signature)

CE

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name :	**HK Greatmade Tech Limited**
Manufacturer's Address :	**6th, B Building , PinChuangYuan Science Technology, ShuiDou New Village ,LongHua town . Shenzhen City , Guang Dong Province , China**
Product :	**Spo2 Adapter cable, Class I**
Type Designation/Trademark :	**Spo2 Adapter cable**

Product Part No. Of Manufacturer: EX001,EX001-D,EX002,EX003,EX004, EX005, EX006,EX007, EX008,EX008-M,EX009,EX010,EX011,EX012,EX013,EX014,EX015,EX016,EX016-M,EX017,EX018,EX019,EX020,EX020-B,EX020-G,EX020L,EX021,EX022,EX023,EX024,EX025,EX025-M,EX025-L,EX026,EX027,EX028,EX029,EX030,EX031,EX032,EX033,EX033-X,EX034,EX035,EX036,EX037,EX038,EX039,EX040,EX041,EX042,EX043,EX044,EX045,EX046,EX047,EX048,EX049,EX050, EX051,EX052,EX053,EX0-53-M,EX054,EX055,EX056,EX057,EX057-M,EX058,EX059A,EX060,EX061,EX062,EX063,EX064,EX065,EX066,EX067,EX067-M,EX068,EX069,EX070,EX071,EX072,EX073,EX074,EX074-M,EX075,EX076,EX077,EX078,EX078,EX080-5D/5S/7S ,EX033-M

Authorized representative established within the EU (if applicable):

Company Name :

Company Address :

Person responsible for making this declaration

Name, Surname :	**Zhanghanzhi**
Position/Title :	**Director , Owner**

Hereby we declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC

Shenzhen, China

Zhanghanzhi

HK GREATMADE TECH LIMITED 香港格創電子科技有限公司

(Place)

Jan 21th, 2014

(Date)

(Company stamp and legal signature)

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer's Name :	**HK Greatmade Tech Limited**
Manufacturer's Address :	**3th, B Building ,Baifuli Industiral Zone,shanghenglang village , LongHua town .**
	Shenzhen City , Guang Dong Province , China
Product :	**Non-Invasive Blood Pressure Cuff and Air Hose**
Type Designation/Trademark :	**N.I.B.P cuff , Class I**

Product Part No. Of Manufacturer: CF001A, CF002A, CF003A, CF004A,CF004LA,CF004TA , CF001B,CF002B,CF003B, CF004B, CF004LB, CF004TB, CF001C,CF002C,CF003C,CF004C, CF004LC,CF004TC,CF005,CF006.CF007A,CF007B,CF008,CF009,CF010,CF011.CF012,CF013,CF014,CF015,CF016 ,CF1601A/B,CF1602A/B ,CF1701A,CF1702B,CF006-H ,CF017,CF018,CF019 ,CF020. CF1501A/B,CF1502A/B,CF1503A/B, CF1504A/B, CF1505A/B, CF1506A/B, CF1507A/B, CF1508A/B,CF1509A/B,CF1510A/B,CF1512A/B,CF1101A,CF1102A,CF1103A,CF1104A,CF1105A,CF1106A/B,CF1107A/B,CF108A/B,CF1109A/B,CF1110A/B,CF1111A/B,CF1112A/B.CF1601A/B,CF1602A/B,CF1603A/B,CF1701-500A/A1,CF1701-1000A/A1,CF1701-3000A/A1,CF1701-500A1-BL,CF1701-1000A1-BL,CF1701-3000A1-BL,CF1801,CF021,CF022,CF023,CF025,CF026

Authorized representative established within the EU (if applicable):

Company Name :	**Prolinx GmbH**
Company Address :	**Brehmstr. 56,40239, Duesseldorf ,Germany**

Person responsible for making this declaration

Name, Surname :	**ZhangHanzhi**
Position/Title :	**Director , Owner**

Hereby we declares that the Medical device as indicated above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC

Shenzhen China

Zhang Hanzhi

__Mar 19th,2018__

(Place) **(Date)**

(Company stamp and legal signature)

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

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

See attachments for scope

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-11-04
Certificate Registration No.:	SX 60133824 0001
An audit was performed. Report No.:	12018179 027
This Certificate is valid until:	2021-07-26

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2018-10-30

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60133824 0001
Report No.: 12018179 027

Organization: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Scope:

Design and Development, Manufacture, Distibution, Service, Quality Assurance, Planning and Delivery support of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation/Control Units, Camera Heads/Pumps/Monitors/ Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units and Ultrasound Surgical Equipment, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2018-10-30

M.Sc. M. Aihara

Traducere din limba engleză

Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizaţia

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo 192-8507
Japonia

a implementat şi aplică un sistem de management al calităţii pentru dispozitive medicale pentru urmatoarele domenii:

A se vedea ataşamentul pentru domeniul de aplicabilitate

S-a furnizat dovada faptului ca au fost indeplinte cerintele specificate in

EN ISO 13485:2016

Sistemul de management al calităţii este supus unei supravegheri anuale.

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL. 0745471452

Data intrării în vigoare: 04.11.2018
Nr. înregistrare certificat: SX 60133824 0001
A fost efectuat auditul, raport nr. 12018179 027
Acest certificat este valabil până la 26.07.2021

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
M.Sc.M. Aihara

Data, 30.10.2018

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg
Tel: +49 221 806-1371 Fax: +49 221 806-3935 email: cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Nr. inregistrare certificat SX 60133824 0001
Nr. raport: 12018179 027

Organizatie:

Olympus Medical Systems Corp.
2951 Ishikawa-cho
Hachloji-shi, Tokyo 192-8507
Japonia

Domeniul de aplicabilitate: **Proiectare şi dezvoltare, producţie, distribuţie, service, asigurarea calităţii, planificare şi furnizare asistenţă pentru endoscoape, echipamente endoterapie, surse de lumină, procesoare de imagine, unităţi de detectare a poziţiei endoscopului, unităţi de cauterizare electrotermică, sisteme endochirurgicale integrate, unitati de control/reglare endoscopice, capete cameră/pompe/sisteme monitorizare/sisteme înregistrare pentru endoscopie, echipamente electrochirurgicale, endoscoape capsulă şi sisteme, insuflatoare laparoscopice, sisteme de imagistica pentru diagnostic ecografic, unităţi dezinfectare şi echipamente chirurgicale cu ultrasunete, sonde şi traductoare pentru litotriptoare cu ultrasunete, instrumente sterile inactive utilizate împreună cu endoscoape, echipamente sterile pentru endoterapie utilizate împreună cu endoscoape, echipamente sterile inactive utilizate împreună cu sisteme medicale de imagistica pentru diagnostic ecografic şi recipiente apă, tuburi alimentare apă, supape apă şi întrerupătoare de picior pentru pompe.**

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Data, 30.10.2018

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV
Rheinland LGA Products GmbH)
M.Sc.M. Aihara

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL. 0745471452

TÜRKAK
Tıbbi Cihazlar K.Y.S.
TS EN ISO/IEC 17021
AB-0087-YS

ERA MANAGEMENT TEST AND CERTIFICATION SERVICES CORP.
TOSB TAYSAD Oranize Sanayi Bölgesi 1. Cad. 15.Yol No:1, Şekerpınar-
Çayırova / KOCAELİ / TÜRKİYE

The certification body ERA MANAGEMENT TEST AND CERTIFICATION CORP., accredited by TURKAK acc. to TS EN ISO 17021 standard with accreditation number: AB-0087-YS, announces that,

CERTIFICATE

No. SYS-15-00011

acc. to standard

ISO 13485:2003+Cor.1:2009
(EN ISO 13485:2012+AC:2012)

MORTON MEDİKAL SAN. VE TİC. LTD. ŞTİ.

İTOB O.S.B. Ekrem Demirtaş Cad. No:9 Menderes/İzmir-TÜRKİYE

Manufacture and sales of disposable anesthesia, infusion, aspiration products and non-active instruments

Whose quality system has been audited in the scope mentioned and found conform.

Report No. 140109

Certificate valid till: 01.04.2018

The organization is subject to surveillance audit by the Certification body for validity of the certificate. Any changes related to the scope of the certificate must be monitored and approved by ERA YÖNETİM TEST VE BELGELENDİRME HİZMETLERİ A.Ş. The certificate issued might be suspended or withdrawn by the certification body in case of determination of nonconformity acc. to standard based on certification.

Istanbul

Certification Manager

Certificate issue date: 02.04.2015

Last revision date: .....

TÜRKAK
Tıbbi Cihazlar K.Y.S.
TS EN ISO/IEC 17021
AB-0087-YS

ERA YÖNETİM TEST VE BELGELENDİRME HİZMETLERİ A.Ş.
TOSB TAYSAD Oranize Sanayi Bölgesi 1. Cad. 15.Yol No:1, Şekerpınar-
Çayırova / KOCAELİ / TÜRKİYE

TÜRKAK tarafından TS EN ISO 17021 standardına gore akredite edilen AB-0087-YS nolu belgelendirme kuruluşu ERA YÖNETİM TEST VE BELGELENDİRME HİZMETLERİ A.Ş. ilan eder ki;

SERTİFİKA

No SYS-15-00011

ISO 13485:2003+Cor.1:2009
(EN ISO 13485:2012+AC:2012)

standardına göre

MORTON MEDİKAL SAN. VE TİC. LTD. ŞTİ.

İTOB O.S.B. Ekrem Demirtaş Cad. No:9 Menderes/İzmir-TÜRKİYE

Tek kullanımlık anestezi, infüzyon, aspirasyon ürünleri ve aktif olmayan enstrümanların üretimi ve satışı

Kalite yönetim sistemi belirtilen kapsamda denetlenmiş ve uygun bulunmuştur.

Rapor No. 140109

Sertifika geçerlilik tarihi: 01.04.2018

Sertifikaların geçerliliği için ilgili organizasyon Belgelendirme Kuruluşu tarafından yıllık gözetim denetimlerine tabidir. Organizasyonda belgelendirme kapsamıyla ilgili her türlü değişiklik ERA YÖNETİM TEST VE BELGELENDİRME HİZMETLERİ A.Ş. tarafından izlenmeli ve onaylanmalıdır. Yayınlanan sertifika esas alınarak ilgili standarda herhangi bir uygunsuzluk tespit edilmesi halinde bu sertifikanın geçerliliği askıya alınabilir veya sertifika iptal edilebilir.

İstanbul

Belge yayın tarihi: 02.04.2015

Son revizyon tarihi: .....

Belgelendirme Müdürü

TÜRKAK

Tıbbi Cihazlar K.Y.S.
TS EN ISO/IEC 17021
AB-0087-YS

ERA MANAGEMENT TEST AND CERTIFICATION SERVICES CORP.
TOSB TAYSAD Oranize Sanayi Bölgesi 1. Cad. 15.Yol No:1, Şekerpınar-Çayırova / KOCAELİ / TÜRKİYE

The certification body ERA MANAGEMENT TEST AND CERTIFICATION CORP., accredited by TURKAK acc. to TS EN ISO 17021 standard with accreditation number: AB-0087-YS, announces that,

CERTIFICATE

No. SYS-15-00010

acc. to standard

ISO 9001:2008

MORTON MEDİKAL SAN. VE TİC. LTD. ŞTİ.

İTOB O.S.B. Ekrem Demirtaş Cad. No:9 Menderes/İzmir-TÜRKİYE

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Istanbul

Certification Manager

Certificate issue date: 02.04.2015

Last revision date: .....

TÜRKAK
Tıbbi Cihazlar K.Y.S.
TS EN ISO/IEC 17021
AB-0087-YS

ERA YÖNETİM TEST VE BELGELENDİRME HİZMETLERİ A.Ş.
TOSB TAYSAD Oranize Sanayi Bölgesi 1. Cad. 15.Yol No:1, Şekerpınar-Çayırova / KOCAELİ / TÜRKİYE

TÜRKAK tarafından TS EN ISO 17021 standardına gore akredite edilen AB-0087-YS nolu belgelendirme kuruluşu ERA YÖNETİM TEST VE BELGELENDİRME HİZMETLERİ A.Ş. ilan eder ki;

SERTİFİKA

No SYS-15-00010

ISO 9001:2008

standardına göre

MORTON MEDİKAL SAN. VE TİC. LTD. ŞTİ.

İTOB O.S.B. Ekrem Demirtaş Cad. No:9 Menderes/İzmir-TÜRKİYE

Tek kullanımlık anestezi, infüzyon, aspirasyon ürünleri ve aktif olmayan enstrümanların üretimi ve satışı

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İstanbul

Belge yayın tarihi: 02.04.2015

Son revizyon tarihi: .....

Belgelendirme Müdürü