CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
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Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

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

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

GIMA S.p.A.

Sede Operativa / *Operational Headquarter:*
Via Marconi, 1
20060 Gessate, MI - Italia
Sede Legale / *Registered Headquarter*
Via Tommaso Grossi, 2
20121 Milano, MI - Italia

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

Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*
Dispositivi per aerosolterapia / *Aerosol therapy devices*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*
Dispositivi per la misurazione della saturazione di ossigeno / *Oxigen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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Rif. rapporto di audit/ *Ref. audit report:* del/dated 1-2/3/2021

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:11:29

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
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Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1104

Marca / *Brandname:*
VEGA / SUPER VEGA / TOBI / SUPER TOBI / TOBI CLINIC / TOBI HOSPITAL / CLINIC PLUS / HOSPI PLUS

Modello / Model:

Aspiratori chirurgici / Surgical aspirators

Codici / Codes:

28220 ; 28216 ; 28209 ; 28214 ; 28210 ; 28232 ; 28211 ; 28202 ; 28212 ; 28233 ; 28243 ; 28234 ; 28222 ; 28194 ; 28224; 28196 ; 28208 ; 28198 ; 28190 ; 28200 ; 28191 ; 28192 ; 28201 ; 28231 28203 ; 28215 ; 28204 ; 28193 ; 28183 ; 28182

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Kit ORL sterile / Sterile ENT kit

Codici / Codes:

31456

Modello / Model:

Kit pap test / Pap smear kit

Codici / Codes:

29704

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Chief Operating Officer
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Data:25/05/2021 10:11:56

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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:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Modello / Model:

Spatula cervicale monouso sterile in plastica o legno / Disposable sterile plastic or wooden cervical spatula

Codici / Codes:

29745 ; 29748-29749

Modello / Model:

Speculum vaginale monouso sterile perno centrale - mix / Disposable sterile vaginal speculum central pin - mix

Codici / Codes:

29991

Modello / Model:

Speculum vaginale monouso sterile perno centrale - piccolo, medio, grande / Disposable sterile vaginal speculum central pin - small, medium, large

Codici / Codes:

29946 ; 29947 ; 29948

Modello / Model:

Speculum vaginale monouso sterile tache - mix / Disposable sterile vaginal speculum tache - mix

Codici / Codes:

29987

Modello / Model:

Speculum vaginale monouso sterile vite centrale - mix / Disposable sterile vaginal speculum middle screw - mix

Codici / Codes:

29995

Modello / Model:

Speculum vaginale monouso sterile vite laterale - mix / Disposable sterile vaginal speculum side screw - mix

Codici / Codes:

29986

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Chief Operating Officer
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Modello / Model:

Speculum vaginale monouso sterile vite laterale (piccolo, medio, grande) / Disposable sterile vaginal speculum side screw - small, medium, large

Codici / Codes:

29983; 29984 ; 29985 ; 29976; 29977, 29978

Modello / Model:

Tampone di trasport in plastica sterile / Sterile plastic transport swab

Codici / Codes:

29753

Marca / *Brandname:*
Gimabrush Ball / Gimabrush / Gima Collector

Modello / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes

Codici / Codes:

29735 ;29736 ; 29737

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Proctoscopio adulti / Adult proctoscope

Codici / Codes:

25957

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

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

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1102

Modello / Model:

Aerosol a pistone adulti e bambini / Adult and Kids compressor nebulizers

Codici / Codes:

28091 ; 28092

Marca / *Brandname:*
EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Codici / Codes:

28097; 28105

Marca / *Brandname:*
MISTRAL

Modello / Model:

Aerosol professionale a pistone per uso domiciliare / Professional compressor nebulizers for home healthcare environment

Codici / Codes:

28102

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Chief Operating Officer
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Organismo Notificato n. 0476
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 0104

Marca / *Brandname:*
BOSTON / DALLAS / GIMATONO / LONDON / ROMA / TOKIO / TECNICO PROFEXIONAL / DAYTON

Modello / Model:
Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:
32731 ; 32747; 32749 ; 32719 ; 32725; 32726 ; 32709; 32727; 32728; 32738; 32734 ; 32693/10965 ; 32735 ; 32745

Marca / *Brandname:*
SIRIO

Modello / Model:
Manometro Aneroide / Aneroid manometer

Codici / Codes:
32904

Marca / *Brandname:*
YTON

Modello / Model:
Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:
32720; 32703; 32693; 32701

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MDS 7010

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Chief Operating Officer
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Organismo Notificato n. 0476
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*

Modello / Model:

Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital SphygmomanometersWRIST / ARM

Codici / Codes:

32926 ; 32924; 32924 SC

Modello / Model:

Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

Codici / Codes:

32800; 32801

Marca / *Brandname:*
DOMINO

Modello / Model:

Sfigmomanometri Digitali / Digital Sphygmomanometers

Codici / Codes:

32803; 32804

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

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MD 0104, MDS 7010

Modello / Model:

Pulsoximetri / Pulse oximeters

Codici / Codes:

34266; 34282; 34285, 34285-10997, 34340; 34342; 34265; 35091; 35092; 35093; 35095; 35090 ; 35100

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Chief Operating Officer
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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

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

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MD 0104, MDS 7010

Marca / *Brandname:*
DIGIT / DIGIT KIDS FARMAMED

Modello / Model:

NUB -Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

10980

Marca / *Brandname:*
FARMAMED / LINEA F / CARREFOUR / GS /PBpharma / 36.2 T&B / SUCCHIOTTO °C / BASALE / GIMA

Modello / Model:

Termometri clinici digitali classici e flessibili / Digital clinical thermometers classic and flexible

Codici / Codes:

25560; 305026-10945; 25561; 25560-10907; 305027-10946 ; 25608

Marca / *Brandname:*
FARMAMED / LINEA F / GIMA

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

25563 ; 25562

Marca / *Brandname:*
PBpharma /GIMA

Modello / Model:

Termometri clinici digitali auricolari e frontali multifunzione / Digital clinical ear and ahaed multifunction thermometers

Codici / Codes:

25580 ; 25585

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Chief Operating Officer
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CERMET

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Allegato tecnico al Certificato/
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 1301, MD 0104

Modello / Model:

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

Codici / Codes:

27335 ; 27344; 27331

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

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0101, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Cannule di Guedel sterili / Sterile Guedel airways

Codici / Codes:

34431, 34432, 34433, 34434, 34435, 34436, 34437, 34438; 34383; 34439

Modello / Model:

Maschere in silicone autoclavabili / Maschere autoclavabili in silicone GIMA PLUS / Silicone autoclavable face masks / Silicone autoclavable face masks GIMA PLUS

Codici / Codes:

34220, 34221, 34222, 34223, 34224, 34225 ; 34252, 34253, 34254, 34255; 34250

Modello / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks

Codici / Codes:

34424; 34425, 34426, 34427, 34428, 34429

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Chief Operating Officer
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

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

Modello / Model:

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

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

Modello / Model:

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

34257; 34258; 34275; 34279

Modello / Model:

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

34227 ; 34228 ; 34259 ; 34256

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

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1403

Modello / Model:

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

34110 ; 34111

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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:15:10

CERMET

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Allegato tecnico al Certificato/
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Modello / Model:

Kit per rimozione sutura / kit procedurale sutura / Suture removal pack / Suture procedure pack

Codici / Codes:

38950 ; 38951

Tipologia / *Medical Devices:*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Modello / Model:

Forbici per bende di Lister / Forbici chirurgiche standard / Lister bandage scissors / Standard surgical scissors

Codici / Codes:

388xx

Modello / Model:

Pinza di Magill / Pinza di Hartmann per orecchio / Magill forceps / Hartmann ear forceps

Codici / Codes:

388xx

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
Giampiero Belcredi

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

Tipologia / *Medical Devices:*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Modello / Model:

Forbici di Mayo / Forbici di Metzenbaum / Forbici Iris / Forbice ombelicale / Forbice per chirurgia orecchio di Bellucci / Pinze per medicazione standard / Pinze di Hunter-Splinter / Pinze emostatiche di Adson / Pinze emostatiche Halstead-Mosquito / Pinza per dissezione McIndoe / Pinze di Pean / Pinza di Spencer-Wells / Pinza portatamponi di Foerster / Portaghi di Hegar- Mayo / Portaghi di Crile-Wood / Mayo scissors / Metzenbaum scissors / Iris scissors / Umbilical scissors / Bellucci ear scissors / Standard dressing forceps / Hunter-Splinter forceps/ Adson haemostatic forceps/ Halstead-Mosquito dissection forceps / McIndoe dissection forceps/ Pean forceps / Spencer-Wells forceps/ Foerster polypus forceps/ Hegar-Mayo needle holder / Crile-Wood needle holder

Codici / Codes:

388xx ; 389xx

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

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
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Tel +39.051.459.3.111
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E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:16:08

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

SONY MEDICAL PRINTERS

Space saving design: 154x240xh 88 mm, for flexible integration into medical carts

33968

SONY

• 33968 SONY HYBRID GRAPHIC PRINTER UP-X898 MD - black/white
Produces A6 size printings in about 2 seconds, with superb print quality with 325 dpi and grey level of 256 steps.
Can take both analogue video and digital signal inputs.
110-240 V AC, 50/60 Hz.

• 33993 SONY COLOUR PRINTER UP-25 MD
High quality analogue A6 Dye.
Sublimation Printer for use in medical applications.
An ideal technology for making high quality, accurate photographic prints.
See more info on www.gimaitaly.com

33993

SONY ORIGINAL PAPER

SONY

SONY VIDEOPRINTER PAPERS
• 72726 SONY PAPER - UPP-110 HD - box of 10 rolls
High density printing paper - 110 mm x 20 m
• 72727 SONY PAPER - UPP-110 HG - box of 10 rolls
High glossy printing paper - 110 mm x 18 m
• 72728 SONY PAPER UPP-110S - box of 10 rolls
• 72729 SONY PAPER UPP-110HA - box of 10 rolls
• 72735 SONY COLOUR PAPER UPC-21L
(4 ink rolls + 200 supports 144x100 mm)

MITSUBISHI ORIGINAL PAPER

• 72740 MITSUBISHI PAPER
K65HM-CE - box of 4

COMPATIBLE PAPERS FOR SONY AND MITSUBISHI PRINTERS

DURICO

ULTRASOUND COMPATIBLE PAPER FOR VIDEOPRINTERS
Top quality thermal print media perfectly fitting Sony and Mitsubishi thermal printers.
Long lasting image durability for high storage durability
- high humidity and heat resistance for long storage
- strong resistance to water, finger prints and ultrasound gel drops.
Precise, high resolution image reproduction
- first class colour intensity for highest black colour density
- outstanding, bright, sharp and detailed medical image
- high glossy, brilliant, photorealistic reproduction
Trouble-free printing and long-term use of printer
- easy tearing along the cross direction
- minimum curling for flat photo media and easy filing
- built-in anti-electrostatic layer preventing thermal head damage.

72745

72751

GIMA code	Compatibility SONY	Compatibility MITSUBISHI	Paper grade	Size mm x m	Minimum order
72745	UPP-110HG	K91HG/KP91HG	high glossy	110x18	box of 5
72746	UPP-84HG	-		84x12.5	box of 10
72747	UPP-110HD	-	high density	110x20	box of 5
72748	-	K65HM/KP65HM		110x20	box of 5
72749	UPP-210HD	-		210x25	box of 5
72750	UPP110S	-	standard	110x20	box of 5
72751	-	K61S/KP61S/KP61B		110x20	box of 5

COMPATIBLE DEFIBRILLATOR ECG THERMAL PAPER - DIFFERENT BRANDS

GIMA code	MANUFACTURER AND MODEL	Type	Width mm	Length m	Sheet	Marker	Grid*	Min. order
	CORPLUS							
33100	Corplus 3	roll	106	20	-	no	or/red	10
	MINDRAY							
32968	Beneheart D3, D6	roll	50	20	-	no	or/red	20
	HEWLETT PACKARD							
33103	40457C/D, Codemaster 100, XL	roll	50	30	-	no	or/red	20
	NIHON KOHDEN							
33029	Def. TEC 5521, 5531, BSM 2300, 3000	pack	50	100	200	no	or/red	25
32988	Tech-8300	roll	50	30	-	no	or/red	20

GIMA code	MANUFACTURER AND MODEL	Type	Width mm	Length m	Sheet	Marker	Grid*	Min. order
	PHILIPS							
33102	Defibrillator MRX	roll	75	25	-	no	or/red	10
33103	Heartstart XL	roll	50	30	-	no	or/red	20
	PHYSIO CONTROL							
33032	Life Pack 8-9-10	roll	50	23	-	no	or/red	20
33033	Life pack 11-12-15	roll	107	25	-	no	or/red	10
	SCHILLER							
32983	Defigard 6002	pack	80	70	300	yes	or/red	20
	ZOLL							
33106	Defi/1400 (P/N 8000-0300)	pack	90	90	200	yes	or/red	20

*or/red: grid could be orange or red colour

CERTIFICATE

Reg. Number	10164 - M	Valid From	2021-10-14
First issue date	2012-10-15	Last change date	2021-10-14
Valid until	2024-10-14		

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:

Management of design and production, packaging and service of:
General non-active, non-implantable medical devices (except: injection, infusion, transfusion and dialysis; disinfecting, cleaning, rinsing; IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except: extra-corporal circulation, infusion and haemopheresis; stimulation or inhibition, rehabilitation devices and active prostheses; IVF, ART; software; medical gas supply systems and parts thereof), Monitoring devices, Devices for imaging and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices (IVD).
Trade and service of: General non-active, non-implantable medical devices (except: IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except IVF, ART), Devices for imaging (except ionizing radiation), Monitoring devices, Devices for radiation therapy and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices(IVD)

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.

This certificate is composed of 1 page.

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

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

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

SGQ N° 007A

		EC006CI	Kanz EKG cable , ***IEC*** , DDK-16PIN ***>Grabber***			
		EC006D	Kanz EKG cable , ***AHA***, DDK-16PIN >**Snap**			
		EC006DI	Kanz EKG cable , ***IEC*** , DDK-16PIN ***>Snap***			
		OEM-EC006	EKG cable with connectors , 4M cable , 2*16pin Connector			

EC006B

OEM-EC006

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
KANZ	PC-109	EC015A-DI	Kanz EKG cable , ***IEC*** , DB 15PIN >**DIN 3.0mm plug**			
pc-109		EC015B-DA	Kanz EKG cable , ***AHA***, DB 15PIN >**DIN 3.0mm Plug**			
PC-108		EC0015A	Kanz EKG cable , ***IEC*** , DB 15PIN >***Banana 4.0***			
PC-110, 1203 ,1205		EC015B	Kanz EKG cable , ***AHA***, DB 15PIN >***Banana 4.0***			
		EC0015C	Kanz EKG cable , AHA, DB 15PIN >**Grabber**			
		EC015CI	Kanz EKG cable , IEC, DB 15PIN >**Grabber**			
		EC0015D	Kanz EKG cable , AHA, DB 15PIN >**Snap**			
		EC015DI	Kanz EKG cable , IEC, DB 15PIN >**Snap**			

EC015B

Nihon Kohden/Carewell :

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
Nihon Kohden	BJ- 901D	EC007A	Nihon Kohden10-lead EKG cable ,***IEC*** ,NK DB15M >***DIN3.0*** , **No resistor**			
ECG-9620, ECG-9010,	9130K	EC007B	NK9130k EKG cable , AHA, 12ft Grey & DB15M>>***Din3.0, No resistor***			
ECG-9020, ECG-9022,		EC007C	Nihon Kohden10-lead EKG cable ,***AHA***,NK DB15M >***banana 4.0*** , **No Resistor**			
ECG-9110,ECG-9130,		EC007D	Nihon Kohden10-lead EKG cable ,***IEC*** ,NK DB15M >***banana 4.0*** , **No Resistor**			

ECG-9132		EC007E	Nihon Kohden ECGLAB Traadmill test cable , IEC, DB15M->***Snap , No resistor***			
DongJiang		EC007F	Nihon Kohden ECGLAB Traadmill test cable , AHA, DB15M->***Snap ,No resistor***			
ECG-11A,ECG-11B,		EC007G	Nihon Kohden 10-Lead EKG cable , AHA , NK DB15M->***Grabber , No resistor***			
ECG-11D, ECG-32A, (II),		EC007H	Nihon Kohden 10-Lead EKG cable ,IEC, NK DB15M->***Grabber , No resistor***			

ECG-120

Biocare

ECG-101, ECG-101G,

ECG-300, ECG-300G

ECG-1200, ECG-9803

Cardioline ; E1.E1R . E3 , E

Delta 1, 300, 360, C3

Carewell

EC007E

EC007C

EC007A

EC007H

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
Nihon Kohden		EC007A-R	Nihon Kohden10-lead EKG cable ,***IEC*** ,NK DB15M >***DIN3.0*** , **4.7KΩ resistor**			
Cardiofax 6151 /6353		EC007B-R	Nihon Kohden 10-lead EKG cable , AHA, 12ft Grey & DB15M>>***Din3.0, 4.7KΩ resistor***			
Cardiofax EKG-8270/8350		EC007C-R	Nihon Kohden10-lead EKG cable ,***AHA*** ,NK DB15M >***banana 4.0*** , **4.7KΩ resistor**			
8370/8420 /8423		EC007D -R	Nihon Kohden10-lead EKG cable ,***IEC*** ,NK DB15M >***banana 4.0*** , **4.7KΩ resistor**			
/8450/8453/8820/8823		EC007E-R	Nihon Kohden ECGLAB Traadmill test cable , IEC, DB15M->***Snap ,4.7KΩ resistor***			
9130, Cardiofax-O		EC007F-R	Nihon Kohden ECGLAB Traadmill test cable , AHA, DB15M->***Snap ,4.7KΩ resistor***			
Fukuda Cardisuny		EC007G-R	Nihon Kohden 10-Lead EKG cable , AHA , NK DB15M->***Grabber ,4.7KΩ resistor***			
Alpha 1000		EC007H-R	Nihon Kohden 10-Lead EKG cable ,IEC, NK DB15M->***Grabber , 4.7KΩ resistor or***			

Cardisuny alpha 6600A

EC007C-R

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
Nihon Kohden	BR-912D	EC007I	Nihon Kohden ECG-9320 10-lead EKG cable ,***IEC***			

Use with patient input-box JC-901D for resting ECG

Philips (HP)

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
HP/Philips	M3703A/C	EC009A	**HP** EKG cable , ***IEC***, DB15m> ***Banana 4.0***			
M1770A Pagewrier 200i		EC009B	**HP** EKG cable ,***AHA***, DB15m> ***Banana 4.0***			
1772A,M3703C, M2462A		EC009C	***HP*** EKG CABLE and leadwires ,IEC, ***Snap***			
M1771A PageWriter 200 ;		EC009D	***HP*** EKG CABLE and leadwires , ***AHA Snap***			
M1772A PageWriter 100 ;		EC009E	**HP** EKG CABLE and leadwires , IEC, **Grabber**			
PageWriter XLI M1700A		EC009F	***HP*** EKG CABLE and leadwires , ***AHA, Grabber***			
Dr.Lee						

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
HP/ Philips	M1716B	EC021A	HP M1716B EKG leadwire set , ***IEC***, 2PIN > ***Banana 4.0***			
M1700A , 1701A, 1702A ,	M1713B	EC021B	HP M1713B EKG leadwire set ,***AHA***, 2PIN > ***Banana 4.0***			
Trim 1,2.3		EC021C	Hp ECG leadwire set ,**IEC** , 2pin -> **Snap**			
		EC021D	Hp ECG leadwire set ,AHA , 2pin -> **Snap**			
		EC021E	Hp ECG leadwire set ,**IEC** , 2pin -> **Grabber**			
		EC021F	Hp ECG leadwire set ,AHA , 2pin -> **Grabber** .			

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
HP/Philips See below model compatibilities	M1663A	EC044A	HP 10-lead Trunk cable , HP 12pins .2M			
	M1949A	EC044AL	HP 10-lead Trunk cable , HP 12pins .2.7M			
		EC045A	HP 10-lead ECG leadwire , Snap , AHA			
	M1645A+M1604A	EC045AI	HP 10-lead ECG leadwire . Snap, IEC			
	M1971A+M1978A	EC045B	HP 10-lead ECG leadwire , Grabber, AHA			
		EC045BI	HP 10-lead ECG leadwire , Snap , IEC			

Compatible with Philips . 78352C, 78354C, 78834C， Legacy HP patient Monitors
862472 to 862475 C3 Monito862478, 862479 C3 Monitor,863064, 863065, 863066, 863068
SureSigns VM6, VM8 ECG Modules , M1001A/B, M1002A/B Multi-measurement modules
M3000A, M3001A, M3002A MMS X2 , M8102A MP2 Monitor , M8105A MP5 Monitor
M4735A heartStart XL defibrillator monitor , M3535A/M3536A HeartStart MRx Defibrillator Monitor

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
Edan		EC046A	EDAN EKG cable , ***IEC*** , DB15M>***DIN 3.0***			
		EC046AD	EDAN EKG cable , ***AHA*** , DB15M > ***DIN 3.0***			
		EC046B	EDAN EKG cable , ***AHA*** , DB15M >***Banana 4.0***			
		EC046BI	EDAN EKG cable , ***IEC*** , DB15M ***>Banana4.0***			
		EC046C	EDAN EKG cable , ***AHA*** , DB15M ->**Grabber**			
		EC046CI	EDAN EKG cable , ***IEC*** ,DB15M -***>Grabber***			
		EC046D	EDAN EKG cable , ***AHA*** , DB15M->**Snap**			
		EC046DI	EDAN EKG cable , ***IEC*** , DB15M -***>Snap***			

Connector as Schiller

CU Medical

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
CU Medical		EC047IS	CU compible 10-lead ECG cable with leadwire , IEC Round 12pin-> Snap			
		EC047AS	CU compible 10-lead ECG cable with leadwire , AHA, Round 12pin-> Snap			
		EC047IG	CU compible 10-lead ECG cable with leadwire , IEC Round 12pin->Grabber			
		EC047AG	CU compible 10-lead ECG cable with leadwire , AHA, Round 12pin-> Grabber			

Schiller

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
Schiller	AT-1	EC010A	schiller EKG cable , **IEC**, ***DB15M> Banana 4.0***			
AT-102, CS-200, Cardiovit AT-10 plus AT-104 PC, AT-110 **Futuremed** ;all **Cardiette , Astron. BTL , Del Mar** ;910.920, 930 940, 942, 950, 960,970, 980, **Camina**		EC010B	schiller EKG cable , ***AHA***, ***DB15M> Banana 4.0***			
		EC010C	Schiller EKG Cable , ***IEC, DB15M>Grabber***			
		EC010D	Schiller EKG Cable , AHA, ***DB15M>Grabber***			
		EC010E	Schiller EKG Cable , ***IEC, DB15M>Snap***			
		EC010F	Schiller EKG Cable , AHA, ***DB15M>Snap***			

Compatibilities

Petas

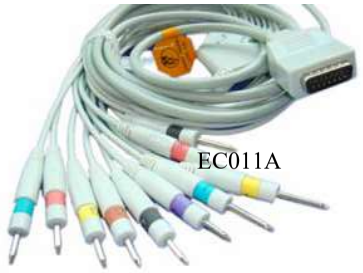
Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	HeartStart M	6-19pcs	Above 20pcs
Petas		EC016A	Petas EKG cable , IEC, Round 12pin > Banana 4.0			
		EC016B	Petas EKG cable , ***AHA***, Round 12pin > Banana 4.0			

Mobimed

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
Mobimed		EC0017A	Mobimed EKG cable , ***IEC***, Round 12pin > ***Banana 4.0***			
		EC0017B	Mobimed EKG cable ,***AHA***, Round 12pin > ***Banana 4.0***			

ShangHai Kohden

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
ShangHai Kohden		EC011A	ShangHai Kohden EKG Cable , ***IEC***, DB15M>***DIN 3.0***			
ECG-6511, 6403		EC011B	ShangHai Kohden EKG Cable ,***AHA***, DB15M>***Banana 4.0***			
ECG-6151, 6504		EC011C	ShangHai Kohden EKG Cable , AHA, DB15M>***DIN 3.0***			
8110P/k. 6353		EC011D	ShangHai Kohden EKG Cable ,IEC, DB15M>***Banana 4.0***			



MORTARA

Compatible Brand	OEM P/N	Greatmade No.	Desceiption (Cable and connector)	1-5pcs	6-19pcs	Above 20pcs
Mortara		EC019A	**Mortara** EKG cable , IEC, DB15M > Banana 4.0 , 4.7KΩ resistance			
Eli100, Eli200		EC019B	**Mortara** EKG cable , ***AHA***, DB15M > Banana 4.0 , 4.7KΩ resistance			
		EC019BA	Mortara EKG CABLE and leadwires , ***AHA***, **Grabber** , 4.7KΩ resistance			
		EC019BI	***Mortara*** EKG CABLE and leadwires , ***IEC, Grabber , 4.7KΩ resistance***			
		EC019C	***Mortara*** EKG CABLE and leadwires ,**AHA, *Snap, 4.7KΩ resistance***			
		EC019CI	***Mortara*** EKG CABLE and leadwires , ***IEC, Snap , 4.7KΩ resistance***			

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 17 12 02231 002

Manufacturer: **Shenzhen Greatmade Tech limited**
3rd Floor, Building B
Baifuli Industrial Zone, Shanghenglang
Huahui Road, Dalang Street
Longhua New District
518109 Shenzhen, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Prolinx GmbH**
Brehmstr. 56
40239 Duesseldorf
GERMANY

Product Category(ies): **Spo2 sensor**

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.: GZ1728501

Valid from: 2018-04-11
Valid until: 2023-04-10

Date, 2018-04-11

Stefan Preiß

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

A1 / 07.09

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 17 12 02231 002

Facility(ies): Shenzhen Greatmade Tech limited
3rd Floor, Building B, Baifuli Industrial Zone, Shanghenglang, Huahui Road, Dalang Street, Longhua New District, 518109 Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

DAkkS CRT2 / 10.13

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

Product Service

CERTIFICATE

No. Q1N 17 12 02231 001

Holder of Certificate: **Shenzhen Greatmade Tech limited**
3rd Floor, Building B
Baifuli Industrial Zone, Shanghenglang
Huahui Road, Dalang Street
Longhua New District
518109 Shenzhen, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen Greatmade Tech limited
3rd Floor, Building B, Baifuli Industrial Zone, Shanghenglang, Huahui Road, Dalang Street, Longhua New District, 518109 Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Spo2 sensor, Patient cable and leadwire, Blood pressure cuff**

Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

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.: GZ1728501

Valid from: 2018-04-11
Valid until: 2021-04-10

Date, 2018-04-11

Stefan Preiß

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