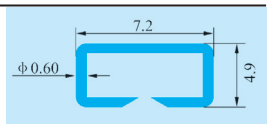
DISPOSABLE SKIN STAPLER



CE 0123

FDA

Multilingual manual and box: GB, FR, IT, ES, PT, DE.

• 25891 DISPOSABLE STERILE SKIN STAPLER - box of 5

Easy to use device with 35 staples made of High Quality 317 L Stainless Steel for medical use.
High sewing up and stapling speed help shorten the time of sewing and avoid cross infection of contagious diseases. Reduced tissue reaction, thinner scar after operation and faster wound healing. Painless and convenient staples removal after the incision has healed up.
For skin closure in operating room, delivery, emergency, outpatient surgery, clinics and physician's office.

3M™ PRECISE™ SKIN STAPLERS

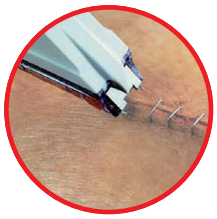
• 25896 3M PRECISE™ SKIN STAPLER 5 staples - sterile - box of 12
• 25897 3M PRECISE™ SKIN STAPLER 15 staples - sterile - box of 12

The disposable Precise skin staplers offer numerous benefits over sutures
- significantly quicker, simpler to use and safer than sutures
- better cosmetic effect
- six times faster than suturing
- no risk of accidental stick injury
- less painful than sutures
- easy to remove.

It comes pre-loaded with 5 or 15 staples (6.5x4.5 mm).
Suitable for simple, recent, open, unbruised wounds. Staples are particularly suitable for scalp wounds as they do not catch on surrounding hair and are more easily identifiable at the time of removal.

CE 0086

3M

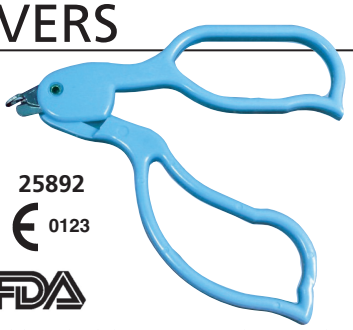


SKIN STAPLE REMOVERS

CE 0476

• 25893 DISPOSABLE SKIN STAPLE REMOVER 11 cm - sterile - box of 50

Suitable for use with most brands of skin staples. It combines functionality with cost effectiveness.



CE 0123

FDA

• 25892 DISPOSABLE REMOVER FORCEPS - sterile - box of 20 pcs.

Practical disposable forceps for removing regular and wider size staples. Plastic handle and stainless steel tips.

3M

CE 0086

• 25895 SR-3 DISPOSABLE SKIN STAPLE REMOVER - sterile - box of 10 pcs.

The scissor-like action of the 3M SR-3 provides ergonomic grip and removes staples in the same direction they were implented, making removal simple. Plastic handle and stainless steel tips.

• 26737 S/S SPENCER SCISSORS - 13 cm
• 26722 S/S MICHEL STITCH REMOVER FORCEPS - 12 cm

BONEWAX - STERILE

• 23000 TRUWAX STERILE SURGICAL BONEVAX 2.5 g - box of 12

Equivalent Ethicon brand: BONE WAX

Truwax is a sterile bone wax used to control bleeding from bone surfaces during surgical procedures by providing hemostasis from bone injuries and cuts. It works like a mechanical barrier, thorugh a tamponade effect, it blocks pores and channels of cut or damaged bone. Made from sterile mixture of beeswax paraffin wax and isopropyl palmitate. Materials ensure excellent malleability. Multilingual manual and box: GB, FR, IT, ES, PT, DE, GR.

MDR Certified

23000

TECHNICAL SPECIFICATIONS

Composition:	Bees wax I.P., White Hard Paraffin Wax, I.P., Iso Propyl Palmitate, U.S.P.
Color:	opaque white
Odour:	characteristic odour
Sterilization:	gamma radiation
Shelf life:	5 years
Packing:	2.5 g per unit pack

CE 2265

CLINICEL OXIDIZED REGENERATED CELLULOSE

CLINICEL OXIDIZED REGENERATED CELLULOSE

Equivalent Ethicon brand: SURGICEL

Features
- absorbable hemostat
- made from oxidized regenerated cellulose (plant based product)
- malleable and flexible

Applications
- Neurosurgery: operative intervention into the cerebrum, ventricular system, spinal surgery
- Cardiac Surgery: valve replacement surgery, sterna medullary bleeding, approaches to the skull base, cerebrovascular surgery
- Gynecological surgeries: uterine wall perforation
- ENT: posterior epistaxis
- General surgeries: latrogenic perforations

TECHNICAL SPECIFICATIONS

Effective Hemostasis:	in 3-5 minutes
Sterilization:	gamma radiation
Shelf life:	3 years

CE 2265

23005

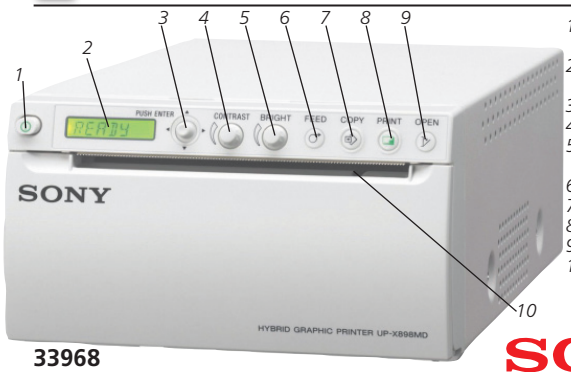
23008

Multilingual manual and box: GB, FR, IT, ES, PT, DE, GR.

MDR Certified

GIMA code	CLINICEL STANDARD - box of 6	cm	inches
23003	Clinicel standard	5.1x7.6	2x3
23004	Clinicel standard	5.1x35.5	2x14
23005	Clinicel standard	10x20	4x8
GIMA code	**CLINICEL FIBRIL TYPE - box of 6**	**cm**	**inches**
23007	Clinicel fibril type	2.5x5.1	1x2
23008	Clinicel fibril type	5.1x10	2x4

SONY MEDICAL PRINTERS



1- Power ON/OFF Switch
2- Printer window LCD display
3- Menu lever
4-CONTRAST control
5- BRIGHT (brightness) control
6- FEED button
7- COPY button
8- H PRINT button
9- OPEN button
10- Paper cutter

33968

• 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. Space saving design: 154x240xh 88 mm, for flexible integration into medical carts.
Multilingual manual: GB, FR, IT, PT.

33961

It incorporates two types of colour adjustment function: RGB and HSV function

• 33993 SONY COLOUR PRINTER UP-25 MD
• 33961 SONY COLOUR PRINTER UP-D25 MD - 21x9.8x39.8 cm
High quality analogue A6 Dye. Sublimation Printer for use in medical applications. An ideal technology for making high quality, accurate photographic prints. USB port (only 33961)
See www.gimaitaly.com

SONY ORIGINAL PAPER

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
High density, high contrast thermal paper, approximately 215 prints per roll.

COMPATIBLE PAPERS FOR SONY AND MITSUBISHI PRINTERS

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
72752	UPP-845	-	high density	84x13.5	box of 10
72753	ULSTAR-110HD	-	matt	110x20	box of 5

CERTIFICATE

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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 all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

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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Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

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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www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:11:56

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 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

Kiwa Cermet Italia S.p.A.
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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 10:12:15

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 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

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:12:32

CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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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 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
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:12:51

CE
Organismo Notificato n. 0476
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CERTIFICATE

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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 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
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:13:13

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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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 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
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:13:36

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 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

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

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:13:57

CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

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 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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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
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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 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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Data:25/05/2021 10:15:10

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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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Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:15:40

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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.
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Chief Operating Officer
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Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:16:08

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2022/05/04
Codice: CERBO0260421

Spett.le

GIMA S.p.A.
P.IVA 00734640154
Via Marconi 1
20060, Gessate (MI)

Oggetto: Nulla Osta per "estensione Nuovo codice 25565 riferita al prodotto FARMAMED/LINEA F/GIMA Waterproof_ Termometri clinici digitali" relativo al Piano di Certificazione MED 26036 in conformità ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni

Gentile Cliente,

In accordo all'Art 120, comma 3, del MDR e alla linea guida -MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD si ritiene la seguente modifica non significativa. alla progettazione o alla destinazione d'uso del dispositivo.

Kiwa Cermet Italia, Organismo Notificato n. 0476, a seguito dell'esito positivo dell'attività di valutazione e di delibera relativa a :

Dispositivi per la misurazione della temperatura corporea (Classe II a, Regola 10) Marchio commerciale: FARMAMED/LINEA F/GIMA Modelli: WATERPROOF – Termometri clinici digitali Nuovo Codice; 25565 che corrisponde a un codice già certificato (25560). Il nuovo codice 25565 è relativo allo stesso prodotto, l'unica differenza è nelle grafiche che contengono lingue aggiuntive rispetto a quelle presenti nel 25560. Tale necessità è dovuta al fatto che l'aggiunta di nuove lingue nel manuale d'uso renderebbe troppo voluminoso il manuale e non entrerebbe nella confezione (scatoletta), quindi non è necessario "separare" le lingue

con piacere comunica che la Sua Azienda ha ricevuto il

Nulla Osta

All'estensione introdotta sopra riportata e all'immissione in commercio del relativo dispositivo medico a far data dalla presente comunicazione.

A seguito di quanto sopra, Le comunichiamo che non sarà emessa nessuna ulteriore revisione del certificato CE attualmente in Suo possesso, e che il certificato sotto menzionato rimane valido fino alla scadenza indicata sul certificate stesso.

Certificato CE MED 26036, rev. 23, data di ultima modifica 24/05/2021

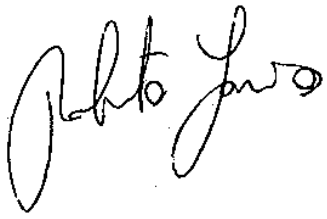
La presente dichiarazione dovrà essere sempre allegata al certificato in Suo possesso.

Vi ricordiamo di farci pervenire su carta intestata, l'identificazione del primo lotto che sarà immesso in commercio a seguito dell'estensione di cui sopra.

Con l'augurio che la collaborazione con Kiwa Cermet Italia possa essere e mantenersi costruttiva anche in futuro, rimaniamo a disposizione per qualsiasi necessità e porgiamo

Cordiali saluti

Kiwa Cermet Italia
Medical Devices Division
Roberto Sanavio



Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2022/05/04
Code: CERBO0260421

Esteemed

GIMA S.p.A.
PIVA 00734640154
Via Marconi 1
20060, Gessate (MI)

Oggetto: Subject: Clearance notice for "New code extension 25565 referring to the product FARMAMED/LINEA F/GIMA Waterproof_Digital clinical thermometers" related to MED 26036 Certification Plan according to Directive 93/42/EEC and s.a.

Dear Customer,

Kiwa Cermet Italia, Notified Body N. 0476, is pleased to inform that following the positive outcome of both documental assessment and decision-making process the following change has been approved:

Devices for measuring body temperature (Class II a, Regulation 10) Trademark: FARMAMED/LINEA F/GIMA Models: WATERPROOF - Digital clinical thermometers New Code: 25565 which corresponds to an already certified code (25560). The new code 25565 relates to the same product, the only difference being in the graphics which contain additional languages to those present in 25560. This is due to the fact that adding new languages to the user manual would make the manual too bulky and would not fit in the box, so there is no need to "separate" the languages.

According to Art 120, indent 3, of MDR and to the MDCG 2020-3 "*Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD*" the above change is considered as not-significant even if an assessment was required.

As a result of the above and by virtue of Art.120, paragraph 1, of the MDR, no further revision of the CE certificate currently in your possession will be issued, which remain valid and registered as:

CE Certificate MED 26036, rev. 23, last modification 24/05/2021

Therefore, this clearance notice shall always be attached to the CE certificate as an integral part.

From the date of this communication your Company is allowed to implement the above addition and to put on the market the related medical devices.

We also remind you; it is mandatory to receive on your company letterhead paper, the identification of the first medical devices batch that will be placed on the market according to the following addition mentioned above.

Hoping the collaboration with Kiwa Cermet Italia can remain constructive and fruitful in the future, We remain at your disposal for any other needs you may have

Kind regards

Kiwa Cermet Italia
Medical Devices Division
Roberto Sanavio

Spettabile
GIMA S.P.A.
VIA TOMMASO GROSSI, 2
20121 MILANO MI IT - Italia

Sesto San Giovanni 29/08/2024

Ns. rif.: BO/2024/0823/LG-md

Oggetto: approvazione della richiesta di variazioni del certificato MED 26036 (ON uscente CE 0476)
Object: approval for request of changes for EC Certificate MED 26036 (Outgoing ON CE 0476)

Con la presente Vi informiamo che la richiesta di variazioni relative al **certificato CE MED 26036** in scadenza il 26/05/2024 da Voi richiesta è stata approvata ai sensi dell'articolo 120(3) di MDR in quanto ritenute non significative.
*We hereby inform You about the approval for request of changes relative to **EC Certificate MED 26036** expiring on 26/05/2024. According to Art. 120(3) of MDR, these changes have been approved as non-significant changes.*

Pertanto, al certificato sopra citato si approva la variazione del fabbricante OEM da GPS S.r.l. a AK MEDICAL S.R.L. (Via del Chioso 8-10, MOZZO (BG) 24030 – Italia).
Therefore, We approve to the above-mentioned certificate the change of the OEM manufacturer from GPS S.r.l. to AK MEDICAL S.R.L. (Via del Chioso 8-10, MOZZO (BG) 24030 - Italy).

La presente lettera dovrà essere presentata dal fabbricante come allegato al certificato.
This letter must be considered as an annex of the certificate.

ICIM S.p.A.

Direzione Gestionale e Aree Territoriali
Managing and Local Area Director
Lucio Galdangelo

ICIM S.p.A.
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Società soggetta all'attività di direzione e coordinamento di ICIM GROUP

Il fabbricante dovrà tempestivamente aggiornare la registrazione dei dispositivi medici interessati e collegarli al certificato CE aggiornato secondo le modalità previste dal decreto del Ministero della salute 21 dicembre 2009.
In caso di dispositivi medici singolarmente registrati e oggetto di rinuncia/revoca della certificazione, è necessario che il fabbricante indichi anche la data di fine immissione in commercio.
Se la variazione approvata riguarda una modifica di natura amministrativa (e.g. nome del fabbricante, indirizzo sede legale, cambio mandatario), il fabbricante deve aggiornare le informazioni nella Banca Dati nazionale dei dispositivi medici. Qualora ci sia una variazione della denominazione del fabbricante è inoltre necessario rinotificare il/i dispositivo/i e collegarlo/i al certificato di nuova registrazione.

The manufacturer shall update the registration of all the related medical devices to link them to the updated EC certificate file according to the procedures set out in the decree of the Ministry of Health of 21 December 2009.
In the case of singularly registered medical devices whose EC certificate is withdrawn or voluntary renounced, the manufacturer shall also specify the date of end of the placing on the market.
If the variation concerns an administrative change (e.g. name of the manufacturer, registered office address, new importer), the manufacturer shall properly update the information in the National Database of medical devices. If there is a change in the name of the manufacturer, it is also necessary to associate the related medical devices to the new manufacturer registration and the related update EC certificate.

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Società soggetta all'attività di direzione
e coordinamento di ICIMGROUP

GIMA S.P.A.

VIA TOMMASO GROSSI, 2 - 20121 MILANO (MI) IT

2024.07.01

Lettera di conferma dell'organismo notificato
Riferimento: Contratto n. 126396, 147782

A chi di dovere,

Conferma dello stato di una acquisizione di contratto formale, per effettuazione di Audit di sorveglianza nell'ambito del Regolamento UE 2023/607 che modifica i Regolamenti (UE) 2017/745 e (UE) 2017/746 per quanto riguarda le disposizioni transitorie per alcuni dispositivi medici e dispositivi medico-diagnostici in vitro

La presente lettera conferma che, ICIM SPA, un Organismo Notificato (NB) designato ai sensi del Regolamento (UE) 2017/745 (MDR) e identificato con il numero 0425 sul NANDO, ha ricevuto una richiesta formale in conformità alla Sezione 4.3, primo comma dell'Allegato VII dell'MDR e ha firmato un accordo scritto in conformità alla Sezione 4.3, secondo comma dell'Allegato VII dell'MDR con il seguente produttore:

GIMA S.P.A.
Sede legale: VIA TOMMASO GROSSI, 2 - 20121 MILANO (MI) IT
Sede operativa: VIA MARCONI, 1 - 20060 GESSATE (MI) IT

I dispositivi oggetto della domanda formale e dell'accordo scritto di cui sopra sono identificati nelle tabelle seguenti. La tabella 1 identifica i dispositivi per i quali è stata ricevuta una domanda MDR, è stato concluso un accordo scritto e per i quali l'NB è anche responsabile dell'adeguata sorveglianza dei dispositivi corrispondenti ai sensi della direttiva applicabile. La tabella 2 identifica i dispositivi per i quali è stata ricevuta una domanda MDR e concluso un accordo scritto, ma per i quali l'ente nazionale di controllo non ha ancora assunto la responsabilità di un'adeguata sorveglianza dei dispositivi corrispondenti ai sensi della direttiva applicabile.

Nel caso di dispositivi coperti da certificati rilasciati ai sensi della direttiva 90/385/CEE (AIMDD) o della direttiva 93/42/CEE (MDD) che sono scaduti dopo il 26 maggio 2021 e prima del 20 marzo 2023, senza essere stati ritirati, questa lettera conferma anche che il fabbricante ha firmato l'accordo scritto ai sensi della MDR entro la data di scadenza del certificato MDD/AIMDD; oppure ha fornito la prova che un'autorità competente di uno Stato membro ha concesso una deroga o un'esenzione dalla procedura di valutazione della conformità applicabile ai sensi dell'articolo 59, paragrafo 1, della MDR o dell'articolo 97, paragrafo 1, della MDR rispettivamente, entro il 20 marzo 2023 per i dispositivi in questione.

Di seguito sono riportati i tempi di transizione che si applicano ai dispositivi oggetto della presente lettera, a condizione che il fabbricante continui a rispettare le altre condizioni specificate nell'articolo 120.3c della MDR (come modificata dalla (UE) 2023/607):

- 26 maggio 2026 per i dispositivi impiantabili su misura di Classe III
- 31 dicembre 2027 per i dispositivi di Classe III e per i dispositivi impiantabili di Classe IIb, escluse le tecnologie ben consolidate (WET - suture, graffette, otturazioni dentali, apparecchi ortodontici, corone dentali, viti, cunei, placche, fili, perni, clip e connettori)
- 31 dicembre 2028 per altri dispositivi di Classe IIb, Classe IIa, Classe I immessi sul mercato in condizioni di sterilità o con funzione di misurazione
- 31 dicembre 2028 per i dispositivi che non richiedono l'intervento di un organismo notificato ai sensi della MDD ma che lo richiedono ai sensi della MDR (ad esempio, i dispositivi di classe I che si qualificano come strumenti chirurgici riutilizzabili)

A nome dell'Organismo Notificato,
ICIM SPA
Piazza Don Enrico Mapelli, 75
20099 Sesto San Giovanni MI
Identificazione su NANDO CE0425

Tabella 1: Dispositivi oggetto della presente lettera e per i quali l'NB è anche responsabile dell'adeguata sorveglianza dei dispositivi corrispondenti ai sensi della direttiva applicabile:

Nome del dispositivo o UDI-DI di base (nell'ambito dell'applicazione MDR)	Classificazione del dispositivo MDR (proposta dal produttore e verificata in fase di pre-applicazione)	Se il dispositivo MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo MDD/AIMDD	Riferimento/i del certificato MDD/AIMDD dei dispositivi oggetto della domanda MDR e identificazione NB
Dispositivi per la misurazione di parametri fisiologici – Bilance pesapersone Astra	**Im**	**//**	**Certificato n. MED 26036-1 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**
Dispositivi per la misurazione di parametri fisiologici – Altimetro, Plicometro, Metro per neonati	**Im**	**//**	**Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**
Strumentario Chirurgico Monouso Sterile	**Is, IIa**	**//**	**Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**
Dispositivi per la misurazione della pressione sanguigna - Sfigmomanometri Aneroidi	**Im**	**//**	**Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**
Dispositivi per la misurazione della pressione sanguigna - Sfigmomanometri Digitali	**IIa**	**//**	**Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**
Dispositivi per la misurazione della temperatura corporea	**IIa**	**//**	**Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**
Dispositivi per rianimazione ed assistenza respiratoria	**IIa**	**//**	**Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**

Nome del dispositivo o UDI-DI di base (nell'ambito dell'applicazione MDR)	Classificazione del dispositivo MDR (proposta dal produttore e verificata in fase di pre-applicazione)	Se il dispositivo MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo MDD/AIMDD	Riferimento/i del certificato MDD/AIMDD dei dispositivi oggetto della domanda MDR e identificazione NB
Dispositivi per aerosolterapia	**IIa**	**//**	**Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**
Dispositivi per la misurazione della saturazione di ossigeno - Pulsoximetri	**IIa**	**//**	**Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**
Dispositivi monouso sterili per ginecologia	**Is**	**//**	**Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**
Dispositivi attivi per l'aspirazione di sostanze e liquidi	**IIa**	**//**	**Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**
Monitor paziente multiparametrici	**IIa, IIb**	**//**	**Certificato n. MED 26036B Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.**

Tabella 2: Dispositivi oggetto della presente lettera e per i quali l'NB NON è responsabile dell'adeguata sorveglianza dei dispositivi corrispondenti ai sensi della direttiva applicabile:

Nome del dispositivo o UDI-DI di base (nell'ambito dell'applicazione MDR)	Classificazione del dispositivo MDR (proposta dal produttore e verificata in fase di pre-applicazione)	Se il dispositivo MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo MDD/AIMDD	Riferimento/i del certificato MDD/AIMDD dei dispositivi oggetto della domanda MDR e identificazione NB
Strumentario chirurgico riutilizzabile	**Ir**	**N.A.**	**N.A.**

Lettera di conferma Cronologia delle revisioni

Data	NB riferimento interno riconducibile ad ogni versione della lettera	Azione
2024.04.01	126396	Emissione iniziale
2024.07.01	126396, 147782	Rev.01

Rimanendo a disposizione per qualsiasi chiarimento in, cogliamo l'occasione per porgere i nostri migliori saluti.

Edoardo Dossena
Product Sales Manager Certificazione Prodotto, Ispezioni e Direttive
ICIM S.p.A.

Flavia Lepore
Direttore Commerciale
ICIM S.p.A.

0328CM_03_IT

GIMA S.P.A.

VIA TOMMASO GROSSI, 2 - 20121 MILANO (MI) IT

2024.07.01

Notified Body Confirmation Letter
Reference: 126396, 147782

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, ICIM SPA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

GIMA S.P.A.
Headquarter: VIA TOMMASO GROSSI, 2 - 20121 MILANO (MI) IT
Operative Unit: VIA MARCONI, 1 - 20060 GESSATE (MI) IT

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)

- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,
ICIM SPA
Piazza Don Enrico Mapelli, 75
20099 Sesto Sam Giovanni MI
Identificazione su NANDO CE0425

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Physiological parameters measuring devices (Scales – ASTRA)	IM	N/A	Certificate nr. MED 26036-1, released Kiwa Cermet Italia spa
Physiological parameters measuring devices (Height meter - Skinfold caliper - Baby measuring meter)	IM	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Sterile single use surgical instrument	Is, IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Blood pressure measuring devices (Aneroid Sphygmomanometers)	IM	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Blood pressure measuring devices (Digital Sphygmomanometers)	IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Body temperature measuring devices	IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Respiratory care and resuscitation devices	IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Aerosol therapy devices	IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Oxigen saturation measuring devices	IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Sterile Single use gynaecology and ENT devices	Is	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Active substances and liquids suctioning devices	IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Multiparameters patient monitors	IIa, IIb	N/A	Certificate nr. MED 26036B, released by Kiwa Cermet Italia spa

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Reusable surgical instruments	**Ir**	**N/A**	**N/A**

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.04.01	126396	Initial issue
2024.07.01	126396, 147782	Rev.01

Remaining at your disposal for any clarification on the content of this offer, we take this opportunity to extend our best regards.

Edoardo Dossena
Product Sales Manager Certificazione Prodotto, Ispezioni e Direttive
ICIM S.p.A.

Flavia Lepore
Direttore Commerciale
ICIM S.p.A.

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	GIMA SPA
Manufacturer address and contact details	Via Tommaso Grossi, 2 20121 Milano – Italy Email: regolatorio@gimaitaly.com Telephone number: +39 029538541 Website: www.gimaitaly.com
Single Registration Number (SRN) (if available)	IT-MF-000011004

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	ICIM SPA □ See attached schedule
Notified body number (if applicable)	0425 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Directive Certificate number(s) to which this confirmation is made (if applicable)	Certificate nr. MED 26036-1, Certificate nr. MED 26036, Certificate nr. MED 26036B □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

X Expired/expires *after* 20 March 2023:

Choose one applicable statement:

X Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

X A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

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- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: GIMA SPA

Location & Date: Gessate, 2024.04.01

Signature, Print Name, Title Nicola Manzoni, Legal Representative

Contact Details (at least email): regolatorio@gimaitaly.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Physiological parameters measuring devices (Scales – ASTRA)	Certificato MED 26036-1 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Physiological parameters measuring devices (Height meter - Skinfold caliper - Baby measuring meter)	Certificato MED 26036 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Sterile single use surgical instrument	Certificato MED 26036 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Blood pressure measuring devices (Aneroid Sphygmomanometers)	Certificato MED 26036 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Blood pressure measuring devices (Digital Sphygmomanometers)	Certificato MED 26036 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Body temperature measuring devices	Certificato MED 26036 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Respiratory care and resuscitation devices	Certificato MED 26036 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Aerosol therapy devices	Certificato MED 26036 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Oxigen saturation measuring devices	Certificato MED 26036 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Sterile Single use gynaecology and ENT devices	Certificato MED 26036 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Active substances and liquids suctioning devices	Certificato MED 26036 incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	
Multiparameters patient monitors	Certificato MED 26036B incl. REV	2024-05-26	Kiwa Cermet Italia S.p.A. n 0476	ICIM SPA n. 0425	2028-12-31	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	GIMA SPA
Manufacturer address and contact details	Via Tommaso Grossi, 2 20121 Milano – Italy Email: regolatorio@gimaitaly.com Telephone number: +39 029538541 Website: www.gimaitaly.com
Single Registration Number (SRN) (if available)	IT-MF-000011004

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	Bureau Veritas Italia SpA □ See attached schedule
Notified body number (if applicable)	1370 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	MED 26036 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26/05/2024 □ See attached schedule
End date of extended validity/transition period	31/12/2028 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

X Expired/expires *after* 20 March 2023:

Choose one applicable statement:

X Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

X A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

Location & Date: Gessate, 2024.04.01

Signature, Print Name, Title Nicola Manzoni, Legal Representative

Contact Details (at least email): regolatorio@gimaitaly.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Ghiaccio istantaneo in busta TNT / TNT (REF 34110) Ghiaccio istantaneo in busta PE (REF 34111)	MED 26036	26-05-2024	KIWA CERMET ITALIA SPA Organismo Notificato n. 0476	Bureau Veritas Italia SpA Organismo Notificato n. 1370	31/12/2028	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Capital € 364.000,00 V.A.T. (IVA) Registration No. IT 00734640154 - Registered in Italy: R.E.A. Mi 477226
Reg. Imp. Tribunale di Milano 00734640154 - Registered Office: Via Tommaso Grossi, 2 – 20121 Milano

February 14, 2024

C/0105/24/GF/mab

To: GIMA S.p.A.
Via Tommaso Grossi, 2
20121 - Milano, (MI)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate n° **MED 26036 rev.23 – Directive 93/42/EEC (MDD)**

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement n.7363548, in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

GIMA S.p.A.
Via Tommaso Grossi, 2
20121 - Milano, (MI)
Italy

Tabella n.1

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**Device name under MDD corresponding to the device under MDR application**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application**
Ghiaccio istantaneo in TNT Ghiaccio istantaneo in PE	IIa	Ghiaccio istantaneo TNT Ghiaccio istantaneo PE	Certificate N. MED 26036 rev.23 issued by NB n. 0476 on 24/05/2021

In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

a. The above-mentioned agreement n.7363548 was signed within 2024/09/26;
b. Bureau Veritas Italia Spa is responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1

As required by EU Regulation 2023/607, the validity of the MDD certificate N° MED 26036 rev.23, is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

Confirmation Letter Revision History

Date	Revision	Action
2024/02/14	0	Initial issue

Gloria Focetola

GLORIA FOCETOLA - Local Technical Manager

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Reg. Imp. e P.IVA 11498640157
Altre Sedi: www.bureauveritas.it/sedi

Soggetta all'attività di direzione e coordinamento da parte di Bureau Veritas SA con sede in Neuilly-sur-Seine - Francia

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www.iqnet-certification.com

CERTIFICATO N. **ICIM-9001-050863-01**
CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GIMA S.P.A.

SEDE CENTRALE / *HEADQUARTER*

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

PER LE UNITÀ OPERATIVE VEDERE L'ALLEGATO
FOR OPERATIVE UNITS SEE ATTACHMENT

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

IAF: 29

Commercializzazione di: Dispositivi Medici (DM), Diagnostici in Vitro (IVD), Dispositivi di Protezione Individuale (DPI), Biocidi (PMC), Dispositivi per Veterinaria, Accessori, Arredi e Supporti ad Uso Medico.

Marketing of: Medical Devices (MD), In Vitro Diagnostics (IVD), Personal Protective Equipment (PPE), Biocides (PMC), Veterinary Devices, Accessories, Furnishings and Supports for Medical Use.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
15/10/2012	15/10/2024	14/10/2027

Vincenzo Delacqua
Rappresentante Direzione / *Management Representative*

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

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Allegato al CERTIFICATO N. **ICIM-9001-050863-01**
Attachment to CERTIFICATE No.

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WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

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Comprende oltre la Sede Centrale citata sul Certificato, anche le seguenti Unità Operative:
In addition to the Headquarter mentioned on the Certificate, it also includes the following Operative Units:

VIA MARCONI, 1 20060 GESSATE MI IT - Italia	Gestione della Progettazione, della Fabbricazione ed Immissione sul Mercato di: Dispositivi per la Misurazione dei Parametri Fisiologici, Dispositivi per Ginecologia ed Odontoiatria, Dispositivi per Aerosolterapia, Dispositivi per Rianimazione ed Assistenza Respiratoria, Dispositivi per Terapia Termica, Strumentario Chirurgico, Monitor Multiparametrici, Diagnostici in Vitro. Commercializzazione di: Dispositivi Medici (DM) e Diagnostici in Vitro (IVD), Dispositivi di Protezione Individuale (DPI), Biocidi (PMC), Dispositivi per Veterinaria, Accessori, Arredi e Supporti ad Uso Medico.
VIA TOMMASO GROSSI, 2 20121 MILANO MI IT - Italia	Sede Legale.

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Certificate

CISQ/ICIM S.P.A. has issued an IQNET recognized certificate that the organization:

GIMA S.P.A.

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

For Operative Units see Annex/Annexes

has implemented and maintains a/an

Quality Management System

for the following scope:

Marketing of: Medical Devices (MD), In Vitro Diagnostics (IVD), Personal Protective Equipment (PPE), Biocides (PMC), Veterinary Devices, Accessories, Furnishings and Supports for Medical Use.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on:	**2024-10-15**
First issued on:	**2012-10-15**
Expires on:	**2027-10-14**

Registration Number:

IT-149834 ICIM-9001-050863-01

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

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IT-149834 ICIM-9001-050863-01

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List of additional locations:

VIA TOMMASO GROSSI, 2 20121 MILANO MI IT - Italia

This annex is only valid in connection with the original certificate number mentioned above.

Il certificato è stato rilasciato in precedenza da un altro CAB.
The certificate has been issued previously by another CAB.

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CERTIFICATO N. **ICIM-13485-050862-02**
CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

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PER LE UNITÀ OPERATIVE VEDERE L'ALLEGATO
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È CONFORME ALLA NORMA

UNI CEI EN ISO 13485:2021

IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Gestione della Progettazione, della Fabbricazione ed Immissione sul Mercato di: Dispositivi per la Misurazione dei Parametri Fisiologici, Dispositivi per Ginecologia ed Odontoiatria, Dispositivi per Aerosolterapia, Dispositivi per Rianimazione ed Assistenza Respiratoria, Dispositivi per Terapia Termica, Strumentario Chirurgico, Monitor Multiparametrici, Diagnostici in Vitro. Commercializzazione di: Dispositivi Medici (DM) e Diagnostici in Vitro (IVD).

Management of the Design, Manufacturing and Placing on the market of: Devices for the Measurement of Physiological Parameters, Devices for Gynecology and Dentistry, Devices for Aerosol Therapy, Devices for Resuscitation and Respiratory Assistance, Devices for Thermal Therapy, Surgical Instruments, Multiparametric Monitors, In Vitro Diagnostics. Marketing of: Medical Devices (DM) and In Vitro Diagnostics (IVD).

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
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Vincenzo Delacqua
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Allegato al CERTIFICATO N. **ICIM-13485-050862-02**
Attachment to CERTIFICATE No.

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which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2024-10-15**
First issued on: **2012-10-15**
Expires on: **2027-10-14**

Registration Number:
IT-149833 ICIM-13485-050862-02

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

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