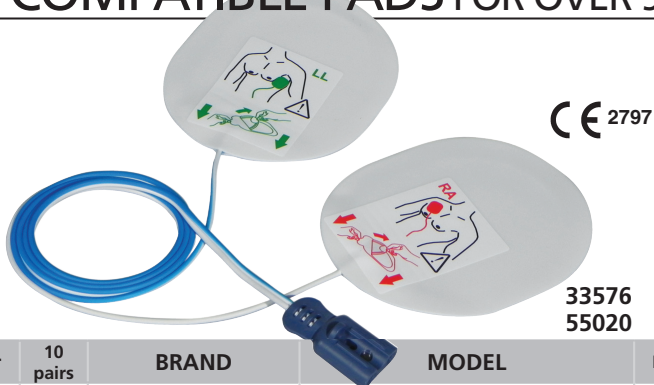


COMPATIBLE PADS FOR OVER 90% OF DEFIBRILLATORS ON THE MARKET



ADULT COMPATIBLE PADS - disposable

A range of compatible pads BSI certified for patients >8 years (25 kg) for most defibrillators on the market. Excellent adherence and adequate gel thickness. Includes a couple of pads, cable and connector. Maximum shelf life 30 months (24 months for 33584) from production date. Latex free. Compliance to regulations: Directive 93/42/EEC and amendments. Class IIb medical device. ANSI/AAMI: DF-80; IEC/EN: 60601-1, 60601-2-4; ISO: 10993-1. Multilingual envelope: GB, FR, IT, ES, PT, DE, NL, SE, GR, RU.

Pair	10 pairs	BRAND	MODEL	Pair	10 pairs	BRAND	MODEL
33576	55020	Agilent-Philips	- Heartstream/HeartStart XL M4735A - Heartstream/HeartStart XLT M3500B - HeartStart XL 861290 - HeartStart 4000 M5500B (all with Philips cable M3508A)	33579	55036	Nihon Kohden	Cardiolife TEC 2202 - 2203 - 5500 - 7531 - 7600 - 7700 - 8251 all with cable JC-755V, TEC 5600 - 8300 with cable JC855V
33577	55022	Agilent Hewlett-Packard	- Codemaster 100-XE-XL-XL+ - Heartstream XL, XLT with cable M3507A	33575	55037	Nihon Kohden	Cardiolife TEC 2202 - 2203 - 5500 - 7531 - 7600 - 7700 - JC-765V, TEC 5600 - 8300 with cable JC855V
33579	55036	Artema Innomed	- Cardio Aid 100 - 200 - 200B - 360B - XL - XL+	33576	55020	Philips Laerdal Medical	- Heartstream Fore Runner I AED models E, S, EM - Heartstart FR AED 940010XX - 940020XX - 940030XX
33579	55036	Artema S&W	- Cardio Aid LS - MC - MC+	33579	55036	S&W	- Tecnoheart Plus (for patient >10 kg)
33587	55048	Bexen Cardio	- Reanibex 200 - 300 - 500 - 700 - 800	33581	55028	Weinmann	- Meducare easy - Meducare standard
33580	55026	Cardiac Science	- Powerheart AED 9200 series - Powerheart AED G3 9300 series (G3, G3 Plus, G3 Pro)	33579	55036	Welch-Allyn	- AED 10 - AED20 - PIC30 - PIC40 - PIC50
33581	55028	Cardiaid	- Cardiaid CT0207	33589	55058	Zoll Medical Corp	- Zoll PD 1200 - 1400 - 1600 - 1700 - 2000 - E - M - R - X series - Pro paq MD
33587	55048	Cardioline	- Elife 700	33585	55060	Zoll Medical Corp	- Aed Plus - AED Pro - AED 3 without CPR function
33448	55030	Cmos Drake	- Futura				
33448	55030	CU Medical System	- i-PAD NF1200				
33578	55034	Defibtech	- DDU 100 Lifeline AED - DDU 120 Lifeline Auto AED				
33579	55036	Drager	- Cardiolog 2000				
33586	55038	Esaote	- MDF SAED - MDF II				
33580	55026	GE	- Responder AED - AED Pro				
33583	55042	GE	- Responder 1100 - 2000 - 3000 (direct connection) - Cardioserv (direct connection) - Dash Responder (direct connection)				
33579	55036	Innomed	- CardioAid 200B - 200 - 100 - 360B - XL+ - XL				
33577	55022	Laerdal	- HeartStart 4000				
33589	55058	M&B	- AED 7000				
33582	55044	Mediana	- HeartOn AED A10				
33584	55046	Mediana	- HeartOn AED A15 (patient >10 kg)				
33609	55050	Metrax Primedic	- Heartsave AED up to S.N. 73944xxxxxx - Heartsave AED-M up to S.N. 73945xxxxxx - Heartsave 6 up to S.N. 73946xxxxxx - Heartsave 6S up to S.N. 73947xxxxxx - Defimonitor XD				
33587	55048	Mindray	- Beneheart D1 - D3 - D6, S&C series				
33579	55036	MRL	- Lite - Lifequest				

COMPATIBLE PADS' CONNECTORS TO DEFIBRILLATOR



PEDIATRIC COMPATIBLE PADS WITH ENERGY REDUCTION SYSTEM

PEDIATRIC* COMPATIBLE PADS - disposable

These pads have an energy reduction system: defibrillator output of 150J (33606) or 200J (33603) is reduced to 50J.

International compliance to regulation as above adult compatible pads.

Latex free.

*CPR guidelines state 8 years as limit age for pediatric treatment, corresponding to about 25 kg according to standard growth curves.



Pair	5 pairs	10 pairs	BRAND	MODEL
33604	55002	-	Cardiac Science	- Powerheart AED 9200 series - Powerheart G3 AED 9300 series (G3, G3 Plus, G3 Pro)
33604	55002	-	GE	- Responder AED, AED Pro
33584	-	55046	Mediana	- HeartOn AED A15 (patient >10 kg)
33606	55006	-	Philips Laerdal Medical	- Heartstart FR2 AED, with ECG module 3840A, M3861A, 3860A
33603	55004	-	Physiocontrol	- Lifepak 500 AED pink socket - Lifepak 1000 AED - Lifepak CR plus AED - Lifepak Express AED
33584	-	55046	Tecno-Gaz	- Tecnoheart Plus (patient >10 kg)

GIMA GREEN F.O. XENON/HALOGEN AND LED LARYNGOSCOPES



GIMA GREEN LARYNGOSCOPES

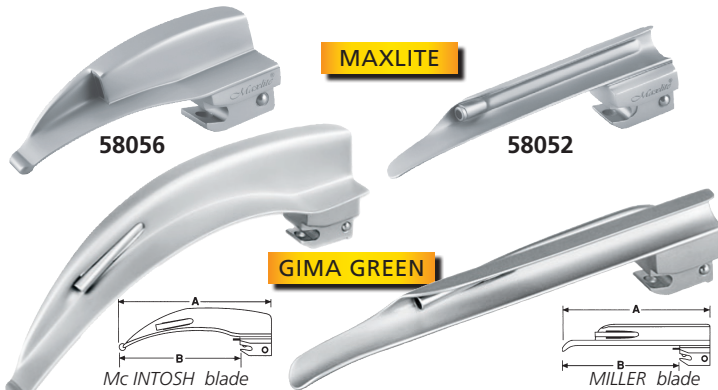
- maximum light transmission thanks to durable and high quality fibres
- specially designed blades for easy intubation
- matt finished to reduce glare
- autoclavable up to 134°C for 5 minutes. Blades autoclavable up to 2,000 times
- compatible to plasma sterilization
- all blades are compatible to BS EN ISO 7376 Green standard handles
- all blades are made of Austenitic Stainless steel thereby making them rust proof
- long life blades. GIMA offers 3 years Warranty
 - a large selection of power sources to use: 'AA' and 'C' type batteries or 2.5 V and 3.5 V rechargeable batteries
 - 2.5 V handles can be used with standard or rechargeable batteries
 - handles are available with 2.5 V and 3.5 V Xenon/Halogen and LED bulbs
 - all blades are non magnetic

Mc INTOSH BLADES

MILLER BLADES

HALOGEN/XENON BATTERY HANDLE

LED BATTERY HANDLE



Gima Green and Maxlite: Miller and Mc-Intosh blades

- Gima Green 4.0 mm Ø F.O. bundle with more than 5,500 individual fibre strands
- Miller Maxlite 3.0 mm Ø bundle with more than 5,000 individual fibre strands
- McIntosh Maxlite 4.5 mm Ø bundle with more than 6,500 individual fibre strands

High quality fibres ensuring excellent light transmission Gima Green and Miller

Maxlite: 7,000 lux with 2.5 V Xenon/Halogen lamp, 12,500 lux with 3.5 V Xenon/Halogen lamp, 18,000 lux with 2.5 LED lamp, 30,000 lux with 3.5 V LED lamp

McIntosh Maxlite: 8,000/14,000/20,000/40,000 lux

GIMA code	"GIMA MAXLITE" FIBRE OPTIC BLADES	A	B
58051	MILLER N° 0 blade - Newborn	80	55
58052	MILLER N° 1 blade - Infant	100	75
58056	Mc INTOSH N° 0 blade - Newborn	82	57
58057	Mc INTOSH N° 1 blade - Infant	93	68
58058	Mc INTOSH N° 2 blade - Child	115	90
58059	Mc INTOSH N° 3 blade - Adult	135	110
58060	Mc INTOSH N° 4 blade - Adult large	155	130
58061	Mc INTOSH N° 5 blade - Adult x-large	176	151

GIMA code	"GIMA GREEN" FIBRE OPTIC BLADES*	A	B
34460	MILLER N° 00 OXY blade - Premature	65	40
34461	MILLER N° 0 blade - Newborn	80	55
34462	MILLER N° 1 blade - Infant	100	75
34463	MILLER N° 2 blade - Child	152	127
34464	MILLER N° 3 blade - Adult	192	167
34469	Mc INTOSH N° 0 blade - Newborn	80	55
34470	Mc INTOSH N° 1 blade - Infant	95	70
34471	Mc INTOSH N° 2 blade - Child	115	90
34472	Mc INTOSH N° 3 blade - Adult	134	109
34473	Mc INTOSH N° 4 blade - Adult large	155	130
34474	Mc INTOSH N° 5 blade - Adult x-large	175	150

*equipped with detachable fibre optic light guide

F.O. LIGHT GUIDE FOR GIMA GREEN BLADES

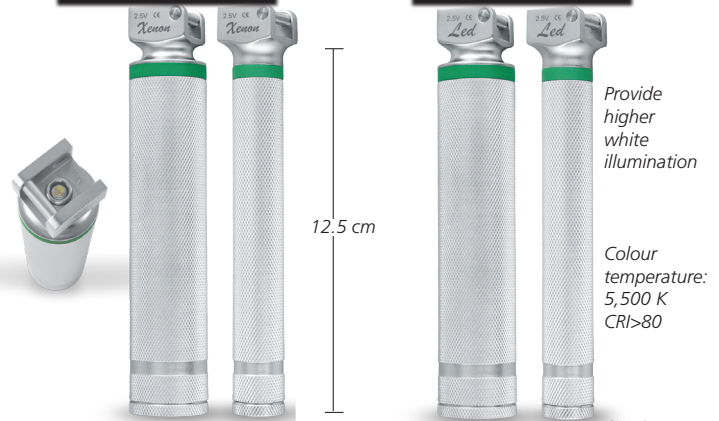
34483	F.O. Light guide for "GIMA Green" Mc Intosh N° 3
34484	F.O. Light guide for "GIMA Green" Mc Intosh N° 4
34486	F.O. Light guide for "GIMA Green" other - specify code

• 31542 GIMA GREEN CHARGING STATION - 100/240 V - 50/60 Hz
It can charge either 2.5 V / 3.5 V NiCa, NimH or Li-ion rechargeable batteries independently of their status of charge. Unit is designed to prevent over charging of batteries. Simultaneously charging of pediatric and adult handle.

Multilingual manual:
GB, FR, IT, ES



Charging station includes pediatric adaptor, wall support, UK, US and EU plug



Xenon/Halogen and LED handles 2.5 V and 3.5 V

- closed battery compartment prevent liquid penetrating inside the battery
- handles are supplied with lamp. Battery not included
- solid metal handle of chromium plated metal

GIMA GREEN RECHARGEABLE BATTERY HANDLES

GIMA code	F.O. XENON/HALOGEN BATTERY HANDLES - 2.5 V
34480	Pediatric rechargeable metal handle (2xAA) - 2.5 V
34481	Adult rechargeable metal handle (2xC) - 2.5 V
34466	Pediatric rechargeable Li-ion battery 2.5 V 1,000 mAh
34467	Adult rechargeable Li-ion battery 2.5 V 2,200 mAh
34485	Halogen bulb 2.5 V (minimum order 6 pcs)

"GIMA GREEN" RECHARGEABLE HANDLES AND BATTERIES 3.5 V - OLD up to lot 8 (ped handle) up to lot 7 (adult handle)

34489	Pediatric rechargeable NiCa battery 3.5 V/700 mAh for 34487
34491	Halogen Bulb 3.5 V

F.O. XENON/HALOGEN BATTERY HANDLE 3.5 V

34456	Pediatric rechargeable metal handle (3.5 V)
34457	Adult rechargeable metal handle (3.5 V)
31540	Pediatric rechargeable Li-ion battery** 3.5 V for 34456, 34487***
31541	Adult rechargeable Li-ion battery** 3.5 V for 34457, 34482, 34488****
for handles sold after may 2013 *since lot 10 ****since lot 12	
34491	Halogen Bulb 3.5 V

F.O. LED BATTERY HANDLES 2.5 V AND 3.5 V*

34476	Pediatric LED rechargeable handle 2.5 V
34477	Adult LED rechargeable handle 2.5 V
34482	Adult rechargeable metal handle - LED light 3.5 V

*LED bulb is assembled with handle in a fixed system and is not replaceable

COMPATIBILITY HANDLE - BATTERY - BULB

GIMA code	Handle		V	Battery			Bulb
	Xenon	LED		Standard 2xAA	Rechargeable 2xC	Li-ion*	
34480	Ped.	-	2.5	yes	no	34466	34485
34481	Adult	-	2.5	no	yes	34467	34485
34456	Ped.	-	3.5	no	no	31540	34491
34457	Adult	-	3.5	no	no	31541	34491
34476	-	Ped.	2.5	yes	no	34466	-
34477	-	Adult	2.5	no	yes	34467	-
34482	-	Adult	3.5	no	no	31541	-

*Li-ion batteries have twice the capacity of an equivalent size NimH batteries.

GIMA S.P.A.
VIA TOMMASO GROSSI, 2 20121 MILANO

2024.01.04

Notified Body Confirmation Letter
Reference: 000126369

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.
VIA TOMMASO GROSSI, 2 20121 MILANO

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
 2099 Sesto San 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)	Class IM	N/A	Certificate nr. MED 26036-1, released Kiwa Cermet Italia spa
Physiological parameters measuring devices (Height meter - Skinfold caliper - Baby measuring meter)	Class IM	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Sterile single use surgical instrument	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Blood pressure measuring devices (Aneroid Sphygmomanometers)	Class IM	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Blood pressure measuring devices (Digital Sphygmomanometers)	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Body temperature measuring devices	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Respiratory care and resuscitation devices	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Aerosol therapy devices	Class IIb	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Oxygen saturation measuring devices	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Sterile Single use gynaecology and ENT devices	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Active substances and liquids suctioning devices	Class IIa	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
Multiparameters patient monitors	Class IIa	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

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.04.01	000126369	Initial issue

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

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


Dott. Dario Bruno
Direttore Commerciale
ICIM S.p.A.


Note:

The following documents are available at www.icim.it

- Certification Regulations related to the services covered by this tender.
- Certification scheme Regulation (EU) 2017/745 (0209CS)
- ICIM Certification Mark User Manual (0260CR)
- ICIM General Rules for the provision of services (0001CR)
- Rules for the Certification of Management Systems (0002CR)
- Product and Service Regulations (0003CR)



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

Pagina / Page 1 di / of 12

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 / *Oxygen 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.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

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



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

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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

Chief Operating Officer

Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476

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
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET



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

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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:

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

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

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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CERMET



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 trasporto 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

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

Pagina / Page 5 di / of 12

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

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
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476



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 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 Aneroidi / 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

Chief Operating Officer
Giampiero Belcredi

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





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 della pressione sanguigna / Blood pressure measuring devices

Modello / Model:

Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital Sphygmomanometers WRIST / 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 / Oxygen 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

CERTIFICATE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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di Kiwa Italia Holding S.r.l.
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Chief Operating Officer
Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476



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 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

Chief Operating Officer

Giampiero Belcredi

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





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

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:14:45





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 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



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:

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

Chief Operating Officer
Giampiero Belcredi

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

Pagina / Page 12 di / of 12

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.

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.
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Chief Operating Officer
Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476



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.

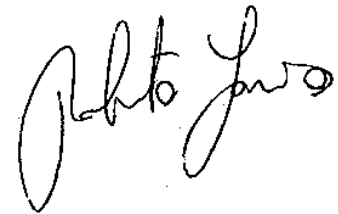


Vi ricordiamo di farci pervenire su carta intestata, l'identificazione del primo lotto che sarà immesso in commercio a seguito dell'estensione di cui sopra.

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



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.

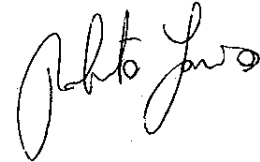
We also remind you; it is mandatory to receive on your company letterhead paper, the identification of the first medical devices batch that will be placed on the market according to the following addition mentioned above.

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



0004MS 0082PRS 0017GHS
0004FRD 0046LSF

Verificatore
accreditato
EMAS
IT-V-0008



ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - Tel. +39 02 725341 - Fax +39 02 72002098

www.icim.it - info@icim.it - legalmail@pec.icimspa.it

Capitale Sociale € 260.000,00 interamente versato - C.F./P.IVA e iscriz. Reg. Imprese n. 12908230159 - R.E.A. n. MI-1596292

Società soggetta all'attività di direzione e coordinamento di **ICIMGROUP**



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.

ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)

Tel. +39 02 725341 - Fax +39 02 72002098

www.icim.it - info@icim.it - legalmail@pec.icimspa.it

Capitale Sociale € 260.000,00 interamente versato

C.F./P.IVA e Iscriz. Reg. Imprese n. 12908230159 - R.E.A. n. MI-1596292

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 pesapersona 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	Ila	//	Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.
Dispositivi per la misurazione della saturazione di ossigeno - Pulsoximetri	Ila	//	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	Ila	//	Certificato n. MED 26036 Organismo Notificato n. 0476 Kiwa Cermet Italia S.p.A.
Monitor paziente multiparametrici	Ila, I Ib	//	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

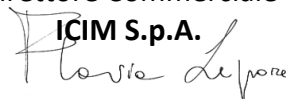
Data	NB riferimento interno riconducibile ad ogni versione della lettera	Azione
2024.04.01	126396	Emissione iniziale
2024.07.01	126396, 147782	Rev.01

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.


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 San 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
Oxygen 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	Ila	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Multiparameters patient monitors	Ila, 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.




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 <input type="checkbox"/> See attached schedule
Notified body number (if applicable)	0425 <input type="checkbox"/> 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.

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 <input type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 <input type="checkbox"/> See attached schedule
End date of extended validity/transition period	2028-12-31 <input type="checkbox"/> 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

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**

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) –Italy
www.gimaitaly.com



ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

- 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

A handwritten signature in black ink, appearing to read 'N. Manzoni', written over a horizontal line.

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	
Oxygen 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)



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 <input type="checkbox"/> See attached schedule
Notified body number (if applicable)	1370 <input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	MED 26036 <input type="checkbox"/> 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.



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

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.

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) – Italy
www.gimaitaly.com



ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

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

A handwritten signature in black ink, appearing to read 'N. Manzoni', written over the contact details line.



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)



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	Ila	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:

- The above-mentioned agreement n.7363548 was signed within 2024/09/26;
- 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 - Local Technical Manager



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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
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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.

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DATA EMISSIONE
FIRST ISSUE
15/10/2012

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Vincenzo Delacqua
Rappresentante Direzione / Management Representative

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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.

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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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CERTIFICATE No. _____

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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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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.

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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:

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).

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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