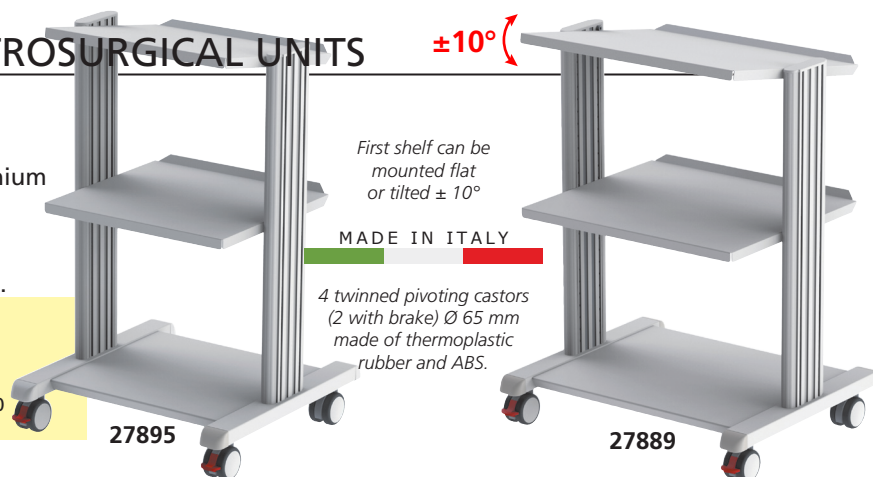


SMART CARTS FOR ELECTROSURGICAL UNITS

- 27895 SMART CART - 2 shelves 40x36 cm + base
 - 27889 SMART CART - 2 shelves 50x42 cm + base
 - 27890 SMART CART - 2 shelves 60x42 cm + base
- Sturdy carts with painted powder steel base and aluminium frame. 2 shelves with protection edge on back, adjustable at different height.
Suitable for all Gima electrosurgical units.
Illustrated assembly instructions. Medical Devices Class I.

TECHNICAL SPECIFICATIONS

	27895	27889	27890
Total load:	80 kg	80 kg	80 kg
Load x shelf:	15 kg	15 kg	15 kg
Size mm:	482x500xh 780	582x500xh 780	682x500xh 780
Weight:	13 kg	15 kg	17 kg



CARTS FOR ELECTROSURGICAL UNITS

Ergonomic trolley designed to hold and carry electrosurgical units (including Argon units). The height of 915 mm with inclined top shelf allows easy reading of the unit's display. The trolley is provided with a second shelf with antiskid raised edges, two drawers at the base and a rear space with securing straps to hold two Argon cylinders. Upright stands can hold optional accessories. Made of epoxy-painted, tempered steel and aluminium. Available version with 4 socket group, fuses box, independent grounding plug, power cable 3m.

TECHNICAL SPECIFICATIONS

Load capacity:	- Total load 200 kg	- Inclined shelf 50 kg
Inclined shelf:	42x45 cm (27864/6)	50x36 cm (27865/7)
Drawers and shelf:	42x36 cm (27864/6)	50x36 cm (27865/7)

GIMA code CARTS FOR ELECTROSURGICAL UNITS

27864	DIATERMO CART - medium
27865	DIATERMO CART - large
27866	DIATERMO CART with power - medium
27867	DIATERMO CART with power - large



ELECTROSURGERY SMOKE EVACUATOR

• 30450 SMOKE EVACUATOR

An aspiration and filtering system for the smokes produced during the surgical procedures. The smokes, generated during the surgical procedures, have a bad, strong and persistent smell. These smokes consist of water vapour, organic gas, visible or invisible solid particles and viral parts. So a good aspiration and filtration eliminates bad smells, reduce the bacteriological and/or viral risks, and improves vision of the zone of the operation area during the laparoscopic procedures.

Activation of the aspiration can be:

- **Automatic**, through the remote electronic system of automatic survey of the activation of the high frequency electrosurgical unit
- **Manual**

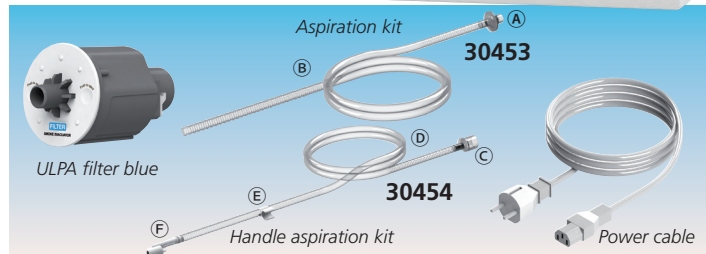
- **Through a foot switch (optional)**

The aspiration flow can be adjusted to suit the specific needs. For laparoscopic procedures there is a specific function L, quickly selectable. Smoke evacuator has an electronic control of the aspiration with the indication of the wearing status of

the filters. There are two different kinds of quickly replaceable ULPA type filters, with active carbons: the BLUE filter is the first filter and it is included with the unit for an initial time of use (5 hours), the RED filter is an optional spare part, developed for a long time use (20 hours). They have connector of 7/8".

- 30451 ULPA FILTER (20 hours) RED for 30450 since S.N. 0216383
- 30452 ULPA FILTER (20 hours) RED for 30450 up to S.N. 0216382
- 30453 ASPIRATION KIT - box of 6
- 30454 HANDLE ASPIRATION KIT - sterile - box of 12
- 30577 MB WATERPROOF FOOTSWITCH - 2 m

MADE IN ITALY



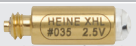
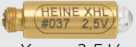
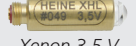
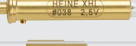
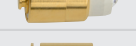
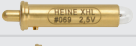
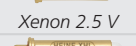
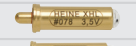
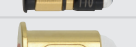
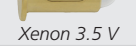
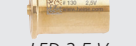
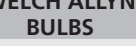
TECHNICAL SPECIFICATIONS

Mains voltage:	230 V (115 V on request)
Mains frequency:	50/60 Hz
Electrical input power:	800 VA
Max vacuum flow rate:	1000 LPM (35 CFM)
Max static suction:	250 mbar (83 in H ₂ O)
Filter type:	ULPA with active carbons
Filter efficiency:	99,999%
Particles diameter:	0.12 micron
Size:	370x144x319 mm
Weight:	4 kg

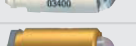
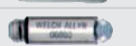
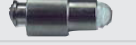
STANDARD ACCESSORIES

ULPA filter (5 hours) blue
Aspiration kit (A) filter + (B) pipe Ø 22 mm, length 2.4 m)
handle aspiration kit (C) adapter 10 mm / 22 mm (D), pipe Ø 10 mm, length 1.8 m,
(E) clip to fix the pipe to the handle, (F) adapter to the handle)
Power cable

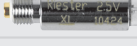
HEINE ORIGINAL BULBS

HEINE BULBS	HEINE ref.	GIMA code	Compatible with following HEINE products
 Xenon 2.5 V	035	31769	Transilluminator Finoff alpha* F.O. and F.O. SP Laryngoscopes - Sanalon handle Glaucotest
 Xenon 2.5 V	037	31771	K100 and Beta* 100, Beta* 100 vet otoscopes Laryngeal mirrors F.O. mini 2000 otoscope Alpha* and Alpha F.O. otoscopes Mini/mini 3000/Alpha/Beta tongue holders
 Xenon 3.5 V	049	31787	F.O. Alpha*, Beta 100, K 100, Beta 100 vet otoscopes; Alpha*, Beta* tongue holders
 Xenon 2.5 V	038	31773	Miroflex ophthalmoscope HFR2 spot retinoscope Delta*10 dermatoscope
 Xenon 2.5 V	041	31774	Fibrilux mini otoscope Mini 2000 combilamp Mini 1000, 2000 cliplamp
 Xenon 2.5 V	042	31780	Alpha* ophthalmoscope Mini 2000 ophthalmoscope Alpha* Focalux, Mini 2000 Focalux Mini Miroflex ophthalmoscope
 Xenon 2.5 V	056	31770	Minilux otoscope Mini 2000 otoscope
 Xenon 2.5 V	069	31781	Beta* 200, 200 M2, 200S ophthalmoscopes - XHL 2.5 V
 Xenon 2.5 V	077	31772	Beta* 200, 200 VET, 400; K 180 otoscopes Lambda 100 retinometer Delta*10 plus dermatoscope
 Xenon 3.5 V	070	31783	Beta 200, 200 M2, 200S ophthalmoscopes - XHL 3.5 V
 Xenon 3.5 V	078	31784	Beta 200, 200 Vet, K180 otoscopes lambda 100 retinometer otoscopes - XHL 3.5 V
 Xenon 2.5 V	084	31782	K180* ophthalmoscope - 2.5 V
 Xenon 2.5 V	105	31776	Mini 3000 F.O. otoscope
 Xenon 2.5 V	106	31777	Mini 3000 ophthalmoscope
 Xenon 2.5 V	107	31778	Mini 3000 combilamp and cliplamp - XHL 2.5 V
 Xenon 2.5 V	109	31779	Mini 3000 dermatoscope
 Xenon 2.5 V	110	31775	Mini 3000 otoscope
 Xenon 3.5 V	089	31786	Alpha*, Beta 200 retinoscopes
 LED 2.5 V	130	31788	Beta 200 LED/halogen retinoscopes

WELCH ALLYN BULBS

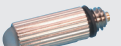
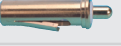
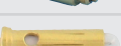
WELCH ALLYN BULBS	W. A. ref.	GIMA code	Compatible with following WELCH ALLYN products
 00200-U	00200-U	32120	Anoscopes: 38800, 380, 385, 395 Illuminators: 41000, 26030 Old products: 235, 77900, 26000, 20100, 21600, 42700, 40510
 03000-U	03000-U	32123	Ophthalmic: 11710, strabismoscope: 12400, episcopes: 47300 Old ophthalmic: 11600, 11605, 11610 Retinoscope: 18000
 03100-U	03100-U	32124	Otoscopes: 25020, 21700, 20200 Handle: 73500, holder: 28100 Illuminators: 27000, 27050, 26530, 41100, 43300 Old otoscopes: 25000, 25200, 20000
 03300-U	03300-U	32125	Ophthalmic: 11511-11500
 03400-U	03400-U	32126	Otoscopes: 24011-24020-24000-24031-21110/1 Handle: 73550, Illuminators: 27200-27250-41110
 03800-U	03800-U	32127	Pan optic: 11810-11820-11800
 04100-U	04100-U	32128	Exam light: 48400-48410
 04200-U	04200-U	32129	Exam light: 48600, 48610-48625-48635, 48700
 04700-U	04700-U	32131	Laryngo: 680, 690, 692 (size 1-2) Old laryngo: 634, 664, 674, 684, 694 (check size)
 04800-U	04800-U	32132	Laryngo: 680 (size 2-4), 690, 692 (size 3-4) Old laryngo: 634, 640, 664, 674, 684, 694 (check size)
 04900-U	04900-U	32133	Ophthalmic: 11720, 11730, 11735, 11620, 11630
 06000-U	06000-U	32134	Laryngo handles: 60813, 60814, 60713, 60815, 60803, 60804
 06500-U	06500-U	32135	Macroview otoscope: 23810, 23820
 07800-U	07800-U	32136	Handle: 73211, 73210, 78000, 73200

RIESTER ORIGINAL BULBS

RIESTER BULBS	RIESTER ref.	GIMA code	Bulb	Compatible with following RIESTER products
 2.7 V	10421	31850	Vacuum 2.7 V	Otoscope uni*/speculight
 2.5 V	10424	31851	XL 2.5 V	May-ophthalmoscope uni*
 3.5 V xenon	10487	31825	XL 3.5 V xenon	Otoscope ri-scope® L1
 2.7 V	10488	31852	Vacuum 2.7 V	Pen-scope® and e-scope® otoscope
 2.5 V	10489	31560	XL 2.5 V	Otoscope pen-scope®/ ri-scope® L1 and e-scope®
 2.5 V	10590	31853	XL 2.5 V	Otoscope uni*
 2.5 V	10600	31854	XL 2.5 V	Otoscope ri-mini®, ri-scope® L2/L3 and e-scope®
 2.5 V	10605	31562	XL 2.5 V	Ophthalmoscope ri-mini/ ri-scope® L1, L2, L3, e-scope®, ri-derma®
 3.5 V	10607	31855	XL 3.5 V	Ri-scope® otoscope L2, L3
 3.5 V	10608	31826	XL 3.5 V	Ri-scope® ophthalmoscope L1, L2, L3
 LED 3.7 V	14041	31561	LED 3.7 V	E-scope F.O otoscope
 LED 3.7 V	14051	31563	LED 3.7 V	E-scope ophthalmoscopes



COMPATIBLE GERMAN BULBS

GIMA BULBS	GIMA code	Compatible with the following products
LARYNGOSCOPE BULBS - MADE IN GERMANY		
 Conventional laryngoscope SMALL bulb 2.7 V	34324	Gima, Riester, And, Kawe, Timesco Truphatek and most of conventional laryngoscopes in the market (generally used for blades N° 00, 0, 1)
 Conventional laryngoscope LARGE bulb 2.7 V	34325	Gima, Riester, And, Kawe, Truphatek, Timesco and most of conventional laryngoscopes in the market (generally used for blades N° 2, 3, 4)
 Xenon halogen bulb for F.O. Laryngoscope and otoscope	34485	Gima, And, Kawe and most of F.O. laryngoscopes in the market. Compatible for products that use Heine Bulb # 035
OTOSCOPE-OPHTHALMOSCOPE BULBS - MADE IN FRANCE-GERMANY		
 Xenon halogen otoscope bulb	31795	Heine mini 3000 otoscopes
 Xenon halogen F.O. otoscope bulb	31796	Heine mini 3000 F.O. otoscopes
 Otoscope bulb 2.5 V	31449	Parker otoscopes and some otoscopes of Riester, Timesco and Kawe
 Ophthalmoscope bulb 2.5 V	31446	Parker ophthalmoscope Parker diagnostic sets
 Xenon halogen bulb for otoscope 2.5 V	31478	Gimalux otoscopes, Kawe and Riester mini otoscopes Compatible for products that use Heine bulb #037
 Halogen bulb for ophthalmoscope and dermatoscope 2.5 V	31479	Parker halogen ophthalmoscope
 Xenon halogen ophthalmoscope bulbs 3.5 V	31428	Gima Xenon - halogen diagnostic sets - ophthalmoscope
OTO-OPHTHALMO-DERMATOSCOPE BULBS - OTHER COUNTRIES		
 Xenon halogen otoscope bulbs 3.5 V	31427	Gima Xenon - halogen diagnostic sets - otoscope

GIMA DISPOSABLE EAR-SPECULUM FOR MINI OTOSCOPES OF DIFFERENT BRANDS

GIMA code	GIMA DISPOSABLE SPECULUM FOR MINI OTOSCOPES - LATEX FREE	Colour	Compatibility		Minimum order
			Direct fit	Fit with connector 31493	
31485	Disposable Mini ear-speculum Ø 2.5 mm - grey		Gima Gimalux, Sigma, Sigma C, Visio 5, Visio 2000 Heine mini 2000, 3000, K180/Beta 200/Beta 400 Riester Ri-Mini, Ri-scope L1-L2, E-scope, Pen-scope Kawe (Picolight, Combilight F030, Eurolight F030) Holtex Colson Luxamed	Gima: 31435-37, 31440-42, 31471, 31473, 31475, 31477, 31480, 31493 (Parker line)	dispenser of 250
31486	Disposable Mini ear-speculum Ø 4 mm - grey				dispenser of 250
31487	Disposable Mini ear-speculum Ø 2.5 mm - black				dispenser of 250
31488	Disposable Mini ear-speculum Ø 4 mm - black				dispenser of 250
31491	Disposable Mini ear-speculum Ø 2.5 mm - black				pack of 100
31492	Disposable Mini ear-speculum Ø 4 mm - black				pack of 100
31495	Disposable Mini ear-speculum mixed colours and Ø				box of 1,000
31496	Disposable Mini ear-speculum Ø 2.5 mm - blue				pack of 100
31497	Disposable Mini ear-speculum Ø 4 mm - blue				pack of 100
31498	Disposable Mini ear-speculum Ø 2.5 mm - green				pack of 100
31499	Disposable Mini ear-speculum Ø 4 mm - green				pack of 100
31501	HEINE dispenser for Mini ear-speculum - empty		31485-8, 31491-2, 31495-9	-	-
GIMA code	CONNECTORS FOR MINI EAR SPECULUM	Colour	To be used with GIMA codes		
31493	Connector to GIMA Parker otoscope for Mini ear-speculum		31435, 31436, 31437, 31440, 31441, 31442, 31471, 31473, 31475, 31477, 31480		
31494	ALLIGATOR connector (supplied with 100 ear speculum)		31435, 31436, 31437, 31440, 31441, 31442, 31471, 31473, 31475, 31477, 31480		



HEINE DISPOSABLE MINI EAR-SPECULUM



RIESTER MINI EAR-SPECULUM



REUSABLE CANNULAS AND EAR SPECULUM

GIMA code	AUTOCLAVABLE SPECULUM FOR PARKER OTOSCOPES - LATEX FREE	Colour	To be used with GIMA code	Also compatible with	Minimum order
31447	Kit 3 autoclavable veterinary speculum Ø 4, 5, 7 mm		31442		One kit
31448	Kit 3 autoclavable speculum Ø 2.5, 3.5, 4.5 mm		31435-37, 31440-42, 31471, 31473, 31475, 31477, 31480	Heine, Kawe, Riester	One kit
31451	Kit of 5 autoclavable speculum Ø 2.5, 3.5, 4.5, 5.5, 9 mm		31435-37, 31440-42, 31471, 31473, 31475, 31477, 31480	Heine, Kawe, Riester	One kit
31453	Kit of 3 metal veterinary cannulas (Ø 4, 5, 6 mm) + 2 slotted metal specula (Ø 7.5 and 9.4 mm)		31422, 31424, 31425		One kit
31483	Pneumatic bulb for Otoscopes		31435/36/37/40/42/71/73/75/77-31520/21/22, 31535	Heine, Kawe, Riester	-

Gima autoclavable ear speculum 31447, 31448, 31451 features:

- made from resilient thermoplastic material
- smooth matte finish surface ensure easy cleaning
- metallic bayonet lock for positive fit to otoscope
- autoclavable at 134°C



2 slotted models with 60 mm opening and round edges, ideal for instrumentation, atraumatic insertion



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:

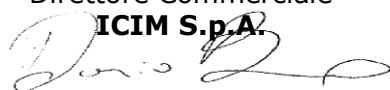
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under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



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Pagina / Page 2 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 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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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

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Pagina / Page 3 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 monouso sterili per ginecologia e otorinolaringoiatria / Sterile Single use gynaecology and ENT devices

Modello / Model:

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

Codici / Codes:

29745 ; 29748-29749

Modello / Model:

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

Codici / Codes:

29991

Modello / Model:

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

Codici / Codes:

29946 ; 29947 ; 29948

Modello / Model:

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

Codici / Codes:

29987

Modello / Model:

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

Codici / Codes:

29995

Modello / Model:

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

Codici / Codes:

29986

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

Chief Operating Officer
Giampiero Belcredi

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Pagina / Page 4 di / of 12

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Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

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

Modello / Model:

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

Codici / Codes:

29983; 29984 ; 29985 ; 29976; 29977, 29978

Modello / Model:

Tampone di 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

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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

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Pagina / Page 5 di / of 12

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Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per aerosolterapia / Aerosol therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1102

Modello / Model:

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

Codici / Codes:

28091 ; 28092

Marca / Brandname:

EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Codici / Codes:

28097; 28105

Marca / Brandname:

MISTRAL

Modello / Model:

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

Codici / Codes:

28102

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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

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Pagina / Page 6 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 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 Aneroido / 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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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

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Pagina / Page 7 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 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

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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

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Giampiero Belcredi

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Pagina / Page 8 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 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

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CERTIFICATE

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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

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Pagina / Page 9 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 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

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Società con socio unico, soggetta
all'attività di direzione e coordinamento
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Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
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E-mail: info@kiwacermet.it
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Pagina / Page 10 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 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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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

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Pagina / Page 11 di / of 12

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

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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

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Pagina / Page 12 di / of 12

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Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Strumentario chirurgico monouso sterile / Sterile single use surgical instrument

Modello / Model:

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

Codici / Codes:

388xx ; 389xx

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

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
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 10:16:08



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 certificato 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.

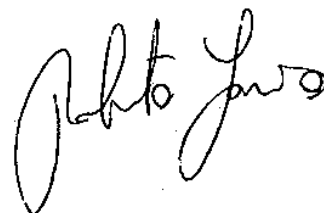


Vi ricordiamo di farci pervenire su carta intestata, l'identificazione del primo lotto che sarà immesso in commercio a seguito dell'estensione di cui sopra.

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

A handwritten signature in black ink, appearing to read "Roberto Sanavio", written in a cursive style.

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.

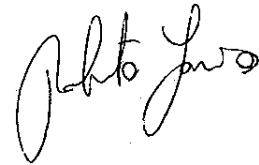
We also remind you; it is mandatory to receive on your company letterhead paper, the identification of the first medical devices batch that will be placed on the market according to the following addition mentioned above.

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

A handwritten signature in black ink, appearing to read "Roberto Sanavio", written in a cursive style.



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
0004PRD

0002PRS
0006LSP

0017GHS

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 **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.

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 – Balance 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	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, Ilb	//	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

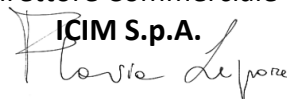
Data	NB riferimento interno riconducibile ad ogni versione della lettera	Azione
2024.04.01	126396	Emissione iniziale
2024.07.01	126396, 147782	Rev.01

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

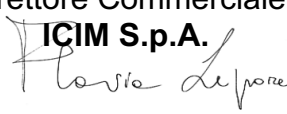
Date	NB internal reference traceable to each version of the letter	Action
2024.04.01	126396	Initial issue
2024.07.01	126396, 147782	Rev.01

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 ☐ 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.



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



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 ☐ 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.



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

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 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)
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:

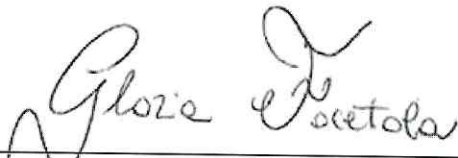
- The above-mentioned agreement n.7363548 was signed within 2024/09/26;
- Bureau Veritas Italia Spa is responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which an agreement has been signed 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



CISQ is a member of



The International Certification Network
www.iqnet-certification.com

CERTIFICATO N.
CERTIFICATE No.

ICIM-13485-050862-02

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

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.
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
FIRST ISSUE
15/10/2012

EMISSIONE CORRENTE
CURRENT ISSUE
15/10/2024

DATA DI SCADENZA
EXPIRING DATE
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



Vincenzo Delacqua

Firmato digitalmente
da: VINCENZO
DELACQUA
Data: 21/05/2025
18:36:48



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale. CISQ
is the Italian Federation of management system
Certification Bodies.



CISQ is a member of



The International Certification Network
www.iqnet-certification.com

Allegato al CERTIFICATO N. **ICIM-13485-050862-02**
Attachment to 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.

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.



MS N° 0004



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale. CISQ
is the Italian Federation of management system
Certification Bodies.

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:

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



This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CGM** China **CQS** Czech Republic
Cro Cert Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FAV** Brazil **FONDONORMA** Venezuela **ICONTEC**
Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece
MSZT Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** Mexico **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia
SIRIM QAS International Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Turkey **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Annex 1 to IQNET Certificate Number:
IT-149833 ICIM-13485-050862-02

GIMA S.P.A.

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

List of additional locations:

VIA MARCONI, 1 20060 GESSATE MI IT - Italia
VIA TOMMASO GROSSI, 2 20121 MILANO MI IT - Italia

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

IQNET Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic
Cro Cert Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC**
Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece
MSZT Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** Mexico **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia
SIRIM QAS International Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com