CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036-1	Revisione / *Revision*	0
Primo rilascio / *First issue date*	2021-05-24	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

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

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

GIMA S.p.A.

:
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 per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*

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/dtd 1-2/3/2021

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:10:31

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036-1	Revisione / *Revision*	0
Primo rilascio / *First issue date*	2021-05-24	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

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

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

Codice NANDO / *NANDO codes:*
MD 0104

Modello / Model:

Bilancia pesapersona / Scales - ASTRA - FAMILY

Codici / Codes:

Astra - cod. 27310 Family - cod. 27301

Codice NANDO / *NANDO codes:*
MD 1301, MDS 7010

Modello / Model:

Bilancia pesapersona / Scales - PEGASO

Codici / Codes:

Pegaso - cod. 27288 (digitale)

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 10:11:07

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2022/03/24
N. Protocollo R 021

Spett.le/ Esteemed

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

Oggetto/ Subject: Comunicazione di riduzione della certificazione CE – Piano di Certificazione MED 26036 / Notification on Reduction of CE Certificate – Certification plan n. MED 26036

Gentile Cliente,

Kiwa Cermet Italia, Organismo Notificato n. 0476, in accordo a quanto da voi formalmente richiesto in data 18/03/2022 comunica di aver registrato per il certificato MED 26036-1 la riduzione della certificazione CE relativa ai prodotti:

Dispositivi per la misurazione dei parametri fisiologici: Bilancia PEGASO e Bilancia FAMILY

A seguito di quanto sopra, Le comunichiamo che per il certificato

Certificato CE MED 26036-1, rev. 0, data di ultima modifica 24/05/2021

non sarà emessa nessuna ulteriore revisione a quanto attualmente in Suo possesso, pertanto la presente dichiarazione dovrà essere sempre allegata al certificato in Suo possesso.

Le richiediamo che, con decorrenza immediata dalla data della presente, non sarà più possibile procedere con la loro immissione in commercio.

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

Dear Customer,

Kiwa Cermet Italia, Notified Body no. 0476, in accordance with to what you formally requested on 18/03/2022, hereby communicates that have activated the procedure of reduction of your CE Certificate relating to the products

Physiological parameters measuring devices: scales PEGASO e scales FAMILY

As a result of the above reduction procedure, We inform you that for the CE Certificate

Certificate CE MED 26036-1, rev. 0, last change date 24/05/2021

no further revision will be issued to what is currently in your possession, therefore this declaration must always be attached to the CE certificate in your possession.

We remind you that, with immediate effect from the date of this communication, it will no longer be possible to put these medical devices on the market.

Hoping the cooperation with Kiwa Cermet can always be positive and effective in the future, we remain at disposal for any other need.

Best Regards

Kiwa Cermet Italia
Medical Devices Division
Cristian Alvisi

DANAK
PROD Reg. nr 7026

FORCE Certification

EU Type Examination Certificate

No. 0200-NAWI-11764

Astra

NON-AUTOMATIC WEIGHING INSTRUMENT

Issued by **FORCE Certification**
EU - Notified Body No. 0200

In accordance with the requirements in Directive 2014/31/EU of the European Parliament and Council.

Issued to **Gima S.p.A.,**
Via Marconi 1
20060 Gessate, Mi,
Italy

In respect of Non-automatic weighing instrument designated Astra.
Accuracy class: III
Maximum capacity:200 kg
Verification scale interval: $e_i \geq 0.1$ kg
Maximum number of verification scale intervals: 2000.

The conformity with the essential requirements in annex 1 of the Directive is met by the application of the European Standard EN 45501:2015 and OIML R76:2006.

The principal characteristics and conditions for certification are set out in the descriptive annex to this certificate.

The annex comprises 6 pages.

Issued on **2022-02-28**
Valid until **2032-02-28**

Jens Hovgård Jensen
2022-02-28

Digitally signed by Jens Hovgård Jensen
jhje@force.dk
Certification Manager

FORCE Certification references:
Task no.: 121-24907.90.10 and ID no.: 0200-NAWI-11764-1

Signatory: Jens Hovgård Jensen

Descriptive annex

Contents

1. Name and type of instrument

The non-automatic weighing instrument designated Astra is a self-indicating scale intended for weighing of persons for medical purpose. The scale is mechanical with analogue indication. The scale is Class III with single-interval.

The scales consist of a mechanical lever system for transferring the load on the load receptor to an equilibrium indicating knife system. The weight is indicated by sliding poises

2. Description of the construction and function

2.1 Construction

Enclosure

The scale housing is made of painted steel. The load tray is covered with anti-slip rubber.

Display

The weight is indicated with two sliding poises sliding over a graduated beam.

The scale may be equipped with a height measuring rod.

The scale shall be equipped with a tilting level meter..

2.2 Functions

2.2.1 Zero-setting

The scale is equipped with a non-automatic zero-setting device.
A small load can be moved by rotating a small screw.

3. Technical data

3.1 Scale

The scales have the following characteristics:

Accuracy class:	III
Weighing range:	single-interval
Number of Verification Scale Intervals:	2000
Maximum capacity (Max):	200 kg
Minimum capacity (Min):	2 kg
Verification Scale Interval:	e = 0.1 kg

3.2 Documents

The documents filed at FORCE Technology (reference No. 121-24907) are valid for the weighing instruments described here.

4. Interfaces and peripheral equipment

4.1 Peripheral equipment

None

5. Conditions for certification

None

6. Special conditions for verification

The scale shall be equipped with a tilting level indicator

7. Securing and location of seals and verification marks

7.1 Securing and sealing

Seals shall bear the verification mark of a notified body or alternative mark of the manufacturer according to ANNEX II, section 2 or 4 of the Directive 2014/31/EU.

7.1.1 Scale

The scale is calibrated with small loads mounted in the two sliding poises.

The access to these loads shall be sealed with tamper proof labels.

8. Location of CE mark of conformity and inscriptions

8.1 Scale

8.1.1 CE mark

CE mark and supplementary metrological marking shall be applied to the instrument according to article 16 of Directive 2014/31/EU

8.1.2 Inscriptions

The inscription plate with manufacturer's trademark and/or name and the type designation is located on the front of the beam

The inscription contains the following information:

- Manufacturer's name and/or logo, postal address of manufacturer, model no., serial no., type examination certificate no., Max_i, Min_i, e_i =, , accuracy class, temperature limits.

9. Pictures

Figure 1 Astra scale.

Figure 2 Sealing of poise w. tamperproof label.

	CERTIFICATO DI CONFORMITÀ AL TIPO BASATA SULLA GARANZIA DELLA QUALITÀ DEL PROCESSO DI PRODUZIONE – MODULO D – DIRETTIVA 2014/31/UE ***CERTIFICATE OF CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS MODULE D – DIRECTIVE 2014/31/EU***	ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO PRD N° 002 B Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC *Signatory of EA, IAF and ILAC Mutual Recognition Agreements*

Documento nr. **D 2022 MI PV 238**
Document nr.

Rina Services S.p.A., quale Organismo Notificato nr. 0474,
Rina Services S.p.A., acting as Notified Body nr. 0474,

CERTIFICA
CERTIFIES

che il sistema qualità adottato da:
that the quality system operated by:

Fabbricante *Manufacturer*	**GIMA S.P.A.**
Indirizzo Sede Legale *Legal Office Address*	**VIA GROSSI TOMMASO 2 – 20121 MILANO (MI)**
Indirizzo Sede Operativa *Operational Office Address*	**VIA MARCONI 1 – 20060 GESSATE (MI)**

ai sensi della Direttiva 2014/31/UE per la produzione, l'ispezione del prodotto finale e la prova dello/degli strumento/i specificato/i sul foglio allegato, è conforme ai requisiti specificati nella **Direttiva 2014/31/UE** per il **Modulo D (Allegato II)**.
pursuant to Directive 2014/31/EU for production, final product inspection and testing of the specified NAWI instrument (s) on the attached sheet, complies with the requirements specified in Directive 2014/31/EU - NAWI for Module D (Annex II).

In base alle procedure della Direttiva 2014/31/UE, la presente certificazione consente al Fabbricante di apporre sui prodotti di seguito descritti le marcature previste, comprendenti tra l'altro, il numero identificativo di Rina Services S.p.A.: **0474**.
According to the procedures of Directive 2014/31/EU, this certification allows the Manufacturer to affix the expected markings on the products described below, including, inter alia, the identification number of Rina Services SpA: 0474.

Rilasciato a *Issued in*	**Genova** *Genoa*	il *on*	21/11/2023	Valido fino al: *Valid until:*	20/11/2026

RINA Services S.p.A.

La validità del presente certificato è subordinata al rispetto dei requisiti dell'Allegato II della Direttiva ed allo svolgimento di verifiche ispettive periodiche di mantenimento da parte di Rina Services S.p.A.. La responsabilità del danno causato da difetti del prodotto è del produttore, come sancito dalla Direttiva delle Comunità Europea n. 374 del 1985.
The validity of this certificate is subjected to the respect of requirements of Annex II of the Directive and to the exploitation of periodical inspection audits carried out by Rina Services S.p.A. The responsibility of damages caused by defects of the product is of the manufacturer, as established by EC Directive n. 374 of 1985.

Questo Certificato è composto da 2 pagine
This Certificate consists of 2 pages

RINA Services S.p.A.
Via Corsica, 12 – 16128 Genova
Tel +39 010 53851
Fax +39 010 5351000
web site: www.rina.org

	CERTIFICATO DI CONFORMITÀ AL TIPO BASATA SULLA GARANZIA DELLA QUALITÀ DEL PROCESSO DI PRODUZIONE – MODULO D – DIRETTIVA 2014/31/UE ***CERTIFICATE OF CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS MODULE D – DIRECTIVE 2014/31/EU***	ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO PRD N° 002 B Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC *Signatory of EA, IAF and ILAC Mutual Recognition Agreements*

Documento nr. **D 2022 MI PV 238**

Document nr.

ELENCO STRUMENTI PER PESARE A FUNZIONAMENTO NON AUTOMATICO SOGGETTI A VALUTAZIONE DI CONFORMITA' SECONDO L'ESAME UE DEL TIPO

LIST OF NAWI INSTRUMENTS SUBJECT TO EU-TYPE EXAMINATION CONFORMITY ASSESSMENT

Strumento per pesare a funzionamento non automatico – modello ASTRA *NAWI type*		
Certificato UE del tipo / Modulo B *EU-type certificate / Module B*	Doc. Nr. 0200-NAWI-11764 Rev. 0	Data 28/02/2022 *Date*
	Emesso da FORCE Certification A/S *Issued by*	Data scadenza 28/02/2032 *Date*

GIMA S.P.A.

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

2024.07.01

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

A chi di dovere,

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

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

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

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

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

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

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

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

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

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

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

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

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

Lettera di conferma Cronologia delle revisioni

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

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

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

Flavia Lepore
Direttore Commerciale
ICIM S.p.A.

0328CM_03_IT

GIMA S.P.A.

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

2024.07.01

Notified Body Confirmation Letter
Reference: 126396, 147782

To whom it may concern,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Confirmation Letter Revision History

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

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

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

Flavia Lepore
Direttore Commerciale
ICIM S.p.A.

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Manufacturer's Declaration

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

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

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

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

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

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

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

We, as the manufacturer declare under our sole responsibility:

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

namely by fulfilling the following conditions:

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

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

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

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

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

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

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

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

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

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

X Expired/expires *after* 20 March 2023:

Choose one applicable statement:

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

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

- **Upclassified devices**

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

Choose one applicable statement:

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

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

- **Quality Management System (QMS)**

Choose one applicable statement:

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

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

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

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

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

Signed for and on behalf of the manufacturer:

Full Company Name: GIMA SPA

Location & Date: Gessate, 2024.04.01

Signature, Print Name, Title Nicola Manzoni, Legal Representative

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

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Schedule of Devices

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

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

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

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