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

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

DICHIARAZIONE DI CONFORMITA'/*DECLARATION OF CONFORMITY*

La Società GIMA S.p.A., con sede operativa in Gessate (MI), in Via Marconi 1, e sede legale in Milano, in Via Tommaso Grossi 2, in qualità di fabbricante del dispositivo medico:
We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

Dispositivo medico / *Medical Device*	**Codice/Code**
BISTURI RETTO - 17,5 cm *STRAIGHT BLADE SCALPEL - 17,5 cm*	26703

Classe di rischio I (Non Sterile), in accordo all'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii., (recepita in Italia con D.lgs 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tale dispositivo:
Risk class I (Not Sterile), according to the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declares, under its own responsibility, that this medical device:

- è conforme ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii., come da fascicolo tecnico conservato in Azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company;
- è fabbricato in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII della sopra citata direttiva.
  is manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

Gessate, 4/1/2020

GIMA S.p.A.
Il legale Rappresentante
The legal Representative
(Nicola Manzoni)

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

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

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.

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

Directive Certificate number(s) to which this confirmation is made (if applicable)	
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ 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)

  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

[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

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

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.

□ Expired/expires *after* 20 March 2023:

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 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:

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 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**

- 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.

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

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:

Full Company Name: GIMA SPA

Location & Date: Gessate 20.03.2025

Signature, Print Name, Title Nicola Manzoni, Legal Representative

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

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

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

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

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)
Reusable surgical instruments	-	-	-	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)

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

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.