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:

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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 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)	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
Oxigen 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)