ENDOMED SOCIETA' A RESPONSBILITA' LIMITATA
VIA UGO LA MALFA, Z.I. S.C. - 04020 SPIGNO SATURNIA (LT) IT - Italia
2024.07.04

Notified Body Confirmation Letter
Reference: 127626

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, 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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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 ICIM 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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
Identification on NANDO CE0425

Table 1: Devices covered by this letter and for which ICIM SPA 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
Electrosurgery instruments	Class IIb	N/A	Certificate nr. IT280018-4 by NB 1370, Bureau Veritas
Instruments for electrosurgery, hysteroscopy, nephroscopy, arthroscopy, cystoscopy, resectoscopy and urethrotomy	Class IIb	N/A	Certificate nr. IT280019-4 by NB 1370, Bureau Veritas
Devices for laparoscopy (Aspiration and coagulation instruments, Trocars)	Class IIb	N/A	Certificate nr. IT304480-1 by NB 1370, Bureau Veritas
Devices for laparoscopy (monopolar laparoscopic forceps)	Class IIa	N/A	Certificate nr. IT304480-1 by NB 1370, Bureau Veritas
Optical instruments	Class IIa	N/A	Certificate nr. IT280020-4 by NB 1370, Bureau Veritas
Ultrasound surgery system	Class IIb	N/A	Certificate nr. IT302169-1 by NB 1370, Bureau Veritas

Table 2: Devices covered by this letter and for which ICIM SPA 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
Surgery instruments	**Class IIa**	**N/A**	**N/A**

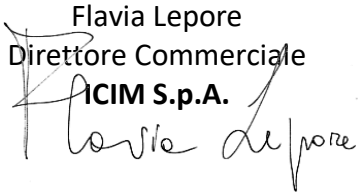
Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.03.18	127626	Initial issue
2024.07.04	127626	Rev.01 close agreement thirt part for surveillance legacy devices

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

Edoardo Dossena
Sales Responsable Manager
Straytegic Industry
ICIM S.p.A.

Flavia Lepore
Direttore Commerciale
ICIM S.p.A.



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