

EMODIAL
VIA FINATI, 4/4A
44124 FERRARA (FE)

2024/05/21

Notified Body Confirmation Letter
Reference: 146956/24 rev. 1

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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SRN Number: IT-MF-000015828

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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
2099 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
N.A.	N.A.	N.A.	N.A.
N.A.	N.A.	N.A.	N.A.
N.A.	N.A.	N.A.	N.A.

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
BETAFIX ALG	Class Is		Certificate n. HD60156672 Expiry 2024-05-25 Notified body: TUV Rheinland
EMOSTAN ALG	Class Is		Certificate n. HD60156672 Expiry 2024-05-25 Notified body: TUV Rheinland
SOVAN ALG	Class Is		Certificate n. HD60156672 Expiry 2024-05-25 Notified body: TUV Rheinland
ALGIWOUND	Class IIb		Certificate n. HD60156672 Expiry 2024-05-25 Notified body: TUV Rheinland

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
DIALYSIS KIT - Peritoneal Dialysis kit - Start/Stop - Application/Removal - Set On/Set Off dialysis Kit - Start/Stop - Application/Removal - Set On/Set Off Catheterism Dressing Kit - Catheter protection dressing kit - EXIT-POCKET	Class Is		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS
DIALYSIS KIT - Start/Stop - Application/Removal - Set On/Set Off dialysis kit containing silver based fistula dressings - Start/Stop - Application/Removal - Set On/Set Off catheterism kit containing silver based exit-site dressing - Peritoneal dressing kit containing silver based exit-site dressing	Class Is		Certificate n. EPG-0288-20 Expiry 2024-05-26 Notified body: ISS Certificate n. QCT-0147-20 Expiry 2024-05-26 Notified body: ISS
FIRST AID DRESSING KIT, STERILE	Class Is		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS
GENERAL DRESSING KIT, STERILE	Class Is		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS
EMOSTAN	Class IIa		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS
BETAFIX	Class IIa		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS
SOVAN	Class IIa		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS
ELASTOP	Class IIa		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS

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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
DIAFIX	Class IIa		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS
FISTOBLOCK ESTOR	Class IIa		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS
TRACH-STOM	Class IIa		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS
TRACHEOSTOMY PAD-RUSCH	Class IIa		Certificate n. QPZ-1929-20 Expiry 2024-05-26 Notified body: ISS

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/21	01	Initial issue

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

Dr. Edoardo Dossena
Product Sales Manager Product Certification,
Inspections and Directives
ICIM S.p.A.


Eng. Flavia Lepore
Sales Director
ICIM S.p.A.
