

DZ MEDICALE SRL

Via Lega Lombarda 8

25036, Palazzolo sull'Oglio (BS)

02/04/2024

**Confirmation letter from the notified body Reference:
Contract no. 71437**

To whom it may concern,

Confirmation of the status of a formal contract acquisition, for carrying out surveillance audits within the scope of EU Regulation 2023/607 which amends Regulations (EU) 2017/745 and (EU) 2017/746 regarding the transitional provisions for some medical devices and in vitro diagnostic medical devices

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

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The devices covered by the formal application and written agreement above are identified in the following tables.

Table 1 identifies devices for which an MDR application has been received, a written agreement has been concluded and for which the NB is also responsible for the appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies devices for which an MDR application has been received and a written agreement concluded, but for which the national control body has not yet assumed responsibility for adequate surveillance of the corresponding devices under the applicable Directive .

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(AIMDD) or Directive 93/42/EEC (MDD) which expired after 26 May 2021 and before 20 March 2023, without having been withdrawn , this letter also confirms that the manufacturer has signed the written agreement under the MDR by the expiry date of the MDD/AIMDD certificate; or has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

Below are the transition times that apply to devices covered by this letter, provided that the manufacturer continues to comply with the other conditions specified in Article 120.3c of the MDR (as amended by (EU) 2023/607):

- May 26, 2026 for Class III custom-made implantable devices • December 31, 2027 for Class III devices and Class IIb implantable devices, excluding well-established technologies (WET - sutures, staples, dental fillings, orthodontic appliances, dental crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb, Class IIa, Class I devices placed on the market in conditions of sterility or with measuring function
- 31 December 2028 for devices that do not require the intervention of a notified body pursuant to the MDD but requiring it under the MDR (e.g., Class I devices that qualify as reusable 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 the adequate surveillance of the corresponding devices pursuant to the applicable directive:

Device name or Basic UDI-DI (within the MDR application)	Classification of MDR device (proposed by the manufacturer and verified in the pre-application phase)	If the MDR device is a replacement device, identification of the corresponding MDD/AIMDD device	Reference(s) of the MDD/AIMDD certificate of the devices covered by the MDR application and identification NB
Vacuum cleaners and accessories	Class IIa	N/A	Certificate 0425-MED-003637-00
Flowmeters ed Humidifiers	Class IIb	N/A	Certificate 0425-MED-003637-00
High pressure devices	Class IIb	N/A	Certificate 0425-MED-003637-00
Bed head beams	Class IIb	N/A	Certificate 0425-MED-003637-00
Emergency unit	Class IIb	N/A	Certificate 0425-MED-003637-00
Terminal Units	Class IIb	N/A	Certificate 0425-MED-003637-00
Class IIb low pressure devices		N/A	Certificate 0425-MED-003637-00
Low pressure pipes	Class IIb	N/A	Certificate 0425-MED-003637-00
Terminal units evacuation	Class IIa	N/A	Certificate 0425-MED-003637-00
Compressed gas/vacuum systems	Class IIb	N/A	Certificate 0425-MED-003637-00
Anesthetic gas evacuation systems	Class IIa	N/A	Certificate 0425-MED-003637-00

Confirmation letter Revision history

Date	NB internal reference attributable to each version of the letter	Action
2024/04/02	71437	Initial issue

Remaining available for any clarification regarding the content of this letter, we take this opportunity to send our best regards.

Edoardo Dossena
Sales Responsible Manager
Strategic Industry
ICIM SpA



Flavia Lepore
Commercial Director
ICIM SpA

