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<Company>

<Address line 1>

<Address line 2>

<Address line 3>

<Date>

Notified Body Confirmation Letter

Reference: XXXXXXXXXX

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, NB Name, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number XXXX 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:

Company Name
Street
25436 City
Country

SRN Number (if available):

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.

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

<NB signatory>
<NB signatory designation>

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
Device 1	Class III Class IIb implantable non- WET device Class IIb excluding Class IIb implantable non-WET Class IIa Class I devices placed on the market in sterile condition	N/A or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives

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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**
	Class I devices with a measuring function Class I devices that qualify as re-usable surgical instruments Class III implantable custom-made device		
Device 2	Class III Class IIb implantable non- WET device Class IIb excluding Class IIb implantable non-WET Class IIa Class I devices placed on the market in sterile condition Class I devices with a measuring function Class I devices that qualify as re-usable surgical instruments Class III implantable custom-made device	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 3			

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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**
Device 1 **Or** **N/A *(to be specified in case there are no devices to be listed in Table 2)***	Class III Class IIb implantable non- WET device Class IIb excluding Class IIb implantable non-WET Class IIa	N/A or Identification of the corresponding device under MDD/AIMDD Or N/A *(to be specified in case there are no devices to be listed in Table 2)*	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives or

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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**
	Class I devices placed on the market in sterile condition Class I devices with a measuring function Class I devices that qualify as re-usable surgical instruments Class III implantable custom-made device Or N/A *(to be specified in case there are no devices to be listed in Table 2)*		*N/A (to be specified in case there are no devices to be listed in Table 2)*
Device 2 **Or** **N/A *(to be specified in case there are no devices to be listed in Table 2)***	Class III Class IIb implantable non- WET device Class IIb excluding Class IIb implantable non-WET Class IIa Class I devices placed on the market in sterile condition Class I devices with a measuring function Class I devices that qualify as re-usable surgical instruments Class III implantable custom-made device Or N/A *(to be specified in case there are no devices to be listed in Table 2)*	N/A or Identification of the corresponding device under MDD/AIMDD Or N/A *(to be specified in case there are no devices to be listed in Table 2)*	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives or *N/A (to be specified in case there are no devices to be listed in Table 2)*

Confirmation Letter Revision History

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Date	**NB internal reference traceable to each version of the letter**	**Action**
YYYY/MM/DD	XXXXXXXXX	Initial issue
YYYY/MM/DD	XXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list

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