Edwards Lifesciences LLC
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Irvine, CA 92614

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April 12, 2024

Subject: Notified Body Confirmation Letter

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, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 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 (dated July 18, 2023) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
United States of America
SRN: US-MF-000007139

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Kevin Nelson, mentored by Gretchen Adams
Project Manager

**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** |
|---|---|---|---|
| Edwards Bovine Pericardial Patch, Model 4700 | Class III | Edwards Bovine Pericardial Patch, Model 4700 | MDD 2103732CE04; NB 0344<br>2103732DE05; NB 0344 |
| INSPIRIS RESILIA Aortic Valve<br>BUDI: 0690103D002IRV000Y9 | Class III | Carpentier-Edwards PERIMOUNT Bioprosthesis model 11500A | MDD 2103732CE04; NB 0344<br>2103732DE04; NB 0344 |
| Carpentier-Edwards PERIMOUNT Magna Mitral Ease Pericardial Bioprosthesis, Model 7300TFX<br><br>BUDI: 0690103D002MME000UF | Class III | Carpentier-Edwards PERIMOUNT Mitral Heart Valve, model 7300TFX | MDD 2103732CE04; NB 0344<br>2103732DE04; NB 0344 |
| Carpentier-Edwards PERIMOUNT Magna Ease Pericardial Aortic Bioprosthesis, Model 3300TFX<br><br>BUDI:0690103D002MEA000QT | Class III | Carpentier-Edwards PERIMOUNT Aortic Heart Valves, model 3300TFX | MDD 2103732CE04; NB 0344<br>2103732DE04; NB 0344 |
| Edwards Inflation Device model 96417<br><br>BUDI: 0690103D002EID000PL | Class Is, Class Im | Edwards Inflation Device model 96417 | MDD 2103732CE04; NB 0344 |

**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 after May 26, 2024:**

| 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 |

## Confirmation Letter Revision History

| Date | Certification Notice (No. + Ver.) | Action |
|---|---|---|
| 2024/04/12 | 2103732CN351.2 | Initial issue |