

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

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Date

29 June 2023

Notified Body Confirmation Letter

Reference: 8003060047

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, TÜV NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 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 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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,

TÜVNORD
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Mühlenberg Kevin
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i. V. Kevin Mühlenberg
Head of Projectmanagement
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

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i. A. Bodo Mestmacher
Specialist Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

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
Pressure Monitoring Set	Class IIb	N/A	04232980886
Leukocyte Filter Set	Class IIb	N/A	04232980886
Gamma Leukocyte Filter Set	Class IIb	N/A	04232980886
Thoracentesis Set	Class IIa	N/A	04232980886
Thoracic Catheter	Class IIa	N/A	04232980886
Arterial Needle	Class IIa	N/A	04232980886
Endotracheal Tube	Class IIa	N/A	04232980886
Reinforced Endotracheal Tube	Class IIa	N/A	04232980886
RAE Endotracheal Tube	Class IIa	N/A	04232980886
Nasogastric Catheter	Class IIa	N/A	04232980886
Stomach Catheter	Class IIa	N/A	04232980886
Feeding Catheter	Class IIa	N/A	04232980886
Manifold / Manifold Pressure	Class IIa	N/A	04232980886
Three -Way Stopcock	Class IIa	N/A	04232980886
Tourniquet Set	Class IIa	N/A	04232980886
IV Cannula	Class IIa	N/A	04232980886
Suction Catheter	Class IIa	N/A	04232980886
Microaggregate Filter Set (Blood Filter Set)	Class IIa	N/A	04232980886
Soft Drain	Class IIa	N/A	04232980886
Oxygen Catheter	Class IIa	N/A	04232980886
Nasal Oxygen Cannula	Class IIa	N/A	04232980886
Oxygen Connecting Tube	Class IIa	N/A	04232980886
Tracheostomy Tube	Class IIa	N/A	04232980886
Extracorporeal PVC Tubing	Class IIa	N/A	04232980886
Extracorporeal Tubing Set	Class IIa	N/A	04232980886
Quick Prime Set	Class IIa	N/A	04232980886
Cardioplegia Set	Class IIa	N/A	04232980886
Wound Drainage Set	Class IIa	N/A	04232980886
Infusion Pump Set	Class IIa	N/A	04232980886
Yankauer Suction Set	Class IIa	N/A	04232980886
Suction Connecting Tube	Class IIa	N/A	04232980886
Surgical Braided Tape	Class IIa	N/A	04232980886
Nelaton Catheter	Class IIa	N/A	04232980886
Tiemann Catheter	Class IIa	N/A	04232980886
Hydrophilic coated urethral Catheter	Class IIa	N/A	04232980886
IV Filter Set	Class IIa	N/A	04232980886
Aspirators	Class IIa	N/A	04232980886
Blood Transfusion Set	Class IIa	N/A	04232980886
Rectal Catheter	Class IIa	N/A	04232980886
Umbilical Catheter	Class IIa	N/A	04232980886
Angiographic Kit	Class IIa	N/A	04232980886

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
B -Soft Kit	Class IIa	N/A	04232980886
Aortic Punch	Class IIa	N/A	04232980886
Gas Sampling Line	Class IIa	N/A	04232980886
External Drainage Set	Class IIa	N/A	04232980886
Vent Catheter	Class IIa	N/A	04232980886
Vessel Cannula	Class IIa	N/A	04232980886
Coronary Artery Retraction Clips	Class IIa	N/A	04232980886
Urine Collection Bag	Class Is	N/A	04232980886
Pleural Drainage Set	Class Is	N/A	04232980886
Central Venous Pressure Set	Class Is	N/A	04232980886
Guedel Airway	Class Is	N/A	04232980886
Spigot	Class Is	N/A	04232980886
Extension Lines	Class Is	N/A	04232980886
Kapkon Connector	Class Is	N/A	04232980886
Straight Connector	Class Is	N/A	04232980886
Straight Luer Connector	Class Is	N/A	04232980886
Y Connector	Class Is	N/A	04232980886
Y Luer Connector	Class Is	N/A	04232980886
Stopper	Class Is	N/A	04232980886
Instopper	Class Is	N/A	04232980886
Umbilical Cord Clamp	Class Is	N/A	04232980886
T.U.R. Set /Arthroscopy set	Class Is	N/A	04232980886
Transfer Set	Class Is	N/A	04232980886
Intravenous Infusion Sets	Class Is	N/A	04232980886
Intravenous Infusion Sets / Flowmeter	Class Is	N/A	04232980886
Intravenous Infusion Sets / Burette	Class Is	N/A	04232980886
B -Safe	Class Is	N/A	04232980886
Intubation Stylet	Class Is	N/A	04232980886
Combi Stopper	Class Is	N/A	04232980886
Urimeter	Class Is	N/A	04232980886
Thoracic Drainage Set	Class Is	N/A	04232980886
Vaginal Specula	Class Is	N/A	04232980886
ENEMA Set	Class Is	N/A	04232980886
I.V. Infusion Set w/B-Flow Flow Regulator	Class Is	N/A	04232980886
Control Syringe	Class Is	N/A	04232980886
Meconium Aspiration Connector	Class Is	N/A	04232980886
Urimeter	Class Im	N/A	04232980886
C.V.P. Set	Class Im	N/A	04232980886
Pleural Drainage Set	Class Im	N/A	04232980886
Volumetric Exerciser (B -Spiro)	Class Im	N/A	04232980886
Infusion Set w/Burette	Class Im	N/A	04232980886
Thoracic Drainage Set	Class Im	N/A	04232980886

Table 2: Devices covered by this letter and for which the NB 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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-07-05	Rev. 0	Initial issue