TÜVNORD

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

Van Oostveen Medical B.V.
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Reference	Contact	Direct Dial	Date
No.: 04232041335 Order 8003069762	E-Mail: medical@tuev-nord.de	Tel.: +49 201 825 2236	20 March 2024

Notified Body Confirmation Letter
Reference: EC-Certificate acc. 93/42/EEC Annex II, No.: 04232041335
Order 8003069762

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:

Van Oostveen Medical B.V.
Herenweg 269
3648 CH WILNIS
Country: The Netherlands
SRN Number: NL-MF-000003481

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 i. V. Digital unterschrieben von Mühlenberg Kevin Datum: 2024.03.20 09:30:23 +01'00'

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

TÜVNORD Digital unterschrieben von Jung Klaus Datum: 2024.03.20 07:35:56 +01'00'

i. A. Klaus Jung
TIC Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD

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
Thermometers mercury free	Class I devices with a measuring function	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Blood pressure meters aneroid	Class I devices with a measuring function	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Syringes	Class I devices placed on the market in sterile condition	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Urine bags	Class I devices placed on the market in sterile condition	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Dropper	Class I devices placed on the market in sterile condition	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Examination gloves sterile	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Blades and Scalps complete	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Blood administration sets	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Blood lancets	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Endotracheal tubes	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Foley balloon catheters (latex)	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH

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
Latex surgical gloves sterile	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Infusion Sets	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Intravenous catheters	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Needles	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Syringes with bypacked needles	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Thermometers digital	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Three Way Stop Cock	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH
Condoms	Class IIb excluding Class IIb implantable non-WET	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH

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
Sphygmomanometers, Electronic	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH

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
Dressing, Nonadherent	Class IIa	N/A	EC-Certificate acc. 93/42/EEC Annex II without (4), Certificate No.: 04232041335; TÜV NORD CERT GmbH

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/19	Rev.0	Initial issue, P111F007 Rev.0