TÜVNORD

TÜV NORD CERT GmbH · P.O. Box 10 32 61 · 45032 Essen · Germany

MEDINORM MEDIZINTECHNIK GMBH
Gewerbepark 7-9
66583 SPIESEN-ELVERSBERG
Germany

TÜV NORD CERT GmbH
Am TÜV 1
45307 Essen, Germany

Phone: +49 201 825-0
Fax: +49 201 825-2517

info.tncert@tuev-nord.de
tuev-nord-cert.com/en

TÜV®

Our / Your Reference	Contact	Direct Dial	Date
8003077047	E-Mail: medical@tuev-nord.de	Tel.: +49 201 825 2236	26 September 2024

Notified Body Confirmation Letter

Reference: 8003077047

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:

MEDINORM MEDIZINTECHNIK GMBH
Gewerbepark 7-9
66583 SPIESEN-ELVERSBERG
Germany
SRN Nummer: DE-MF-000005352

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 Schmidt Caroline
Datum: 2024.09.26 14:43:37 +02'00'

i. V. Caroline Schmidt
Deputy Head of Project Management

Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD
Digital unterschrieben von Falkenberg Edna
Datum: 2024.09.26 14:40:38 +02'00'

i. A. Edna Falkenberg
TIC Manager MDR

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
Katheter,sonstige 15-209	Is	N/A	93/42/EEC Annex V, Ecm 0481 - Z/19/04575D
Katheter,nasale Sauerstoffverabreichung 12-702	Is	N/A	93/42/EEC Annex V, Ecm 0481 - Z/19/04575D
Katheter, Nelaton 10-734	Is	N/A	93/42/EEC Annex V, Ecm 0481 - Z/19/04575D
Katheter, Rektal 10-746	Is	N/A	93/42/EEC Annex V, Ecm 0481 - Z/19/04575D
Drainage, Sammelbehälter 15-270	Is	N/A	93/42/EEC Annex V, Ecm 0481 - Z/19/04575D
Drainage, Wunde 11-305	IIa	N/A	93/42/EEC Annex V, Ecm 0481 - Z/19/04575D
Schlauch, Absaugung 16-779	Is	N/A	93/42/EEC Annex V, Ecm 0481 -Z/19/04575D
Fingertip –	Is	N/A	93/42/EEC Annex V, Ecm 0481 -Z/19/04575D
Katheterstopfen –	Is	N/A	93/42/EEC Annex V, Ecm 0481 -Z/19/04575D,
Absauggerät, tracheal 10-219	Is	N/A	93/42/EEC Annex V, Ecm 0481 -Z/19/04575D
Absauggerät, chirurgisch 10-217	IIa	N/A	93/42/EEC Annex V,
Drainageverbinder –	Is	N/A	93/42/EEC Annex V, Ecm 0481 -Z/19/04575D
Kanüle, sonstige 15-206	Is	N/A	93/42/EEC Annex V, Ecm 0481 -Z/19/04575D
Schale, Zementanmischung 17-221	Is	N/A	93/42/EEC Annex V, Ecm 0481 -Z/19/04575D

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
2024/09/26	Rev.0	Initial issue