TÜVNORD

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

intra special catheters GmbH
Oststr. 2
66780 Rehlingen-Siersburg
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

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Our / Your Reference	Contact	Direct Dial	Date
No.: 44 235 192153	medical@tuev-nord.de	Tel.: +49 201 825 2236	12 July 2024

Notified Body Confirmation Letter
Reference: 44 235 192153

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 00 44 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:

intra special catheters GmbH
Oststr. 2
66780 Rehlingen-Siersburg
Germany
DE-MF-000005178 / DE-PR-000008832 / DE-IM-000008613

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Information for sterile procedure packs:

- Sterile procedure packs are not assigned to any class because they are not "devices" as per EU 2023/745 Art. 2
- Sterile procedure packs are not subject to a conformity assessment procedure in accordance with Art. 52, but to a procedure in accordance with Art. 22 (3)
- The amendments to the transitional periods in accordance with Art. 120 only apply to "devices" of certain classes and therefore expressly not to sterile procedure packs
- Accordingly, even in the case of (voluntary) extended surveillance, the natural or legal person placing sterile procedure packs on the market cannot assume that he can continue to claim the validity of the certificates issued under the 93/42/EEC
- With the above prerequisites TN CERT continues appropriate continued surveillance based on valid contract with the natural or legal person placing sterile procedure packs on the market

On behalf of the Notified Body,

TÜVNORD i. V. Digital unterschrieben von Schmidt Caroline Datum: 2024.07.13 19:53:11 +02'00'

(Deputy) Head of Project Management

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

TÜVNORD Digital unterschrieben von Mestmacher Bodo Datum: 2024.07.16 08:12:34 +02'00'

TIC Manager MDR

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

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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)	**Article No.**	**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**
MICROSELD® PEBA Arterienkatheter nach Seldinger-Technik	305 0xx 305 1xx 305 2xx	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
MICROSELD® PTFE Arterienkatheter nach Seldinger-Technik	302 0xx 302 1xx 302 2xx	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
NEO-PNEUMOCATH®	503 011 503 011E 503 012 503 011E	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
PNEUMOCATH®	503 001E 503 002E 503 003E 503 001 503 002 503 003	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
PNEUMOVENT® Ventil nach Heimlich	504 001 504 002	Class Is	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Stufenadapter / Tube Adapter	011 000	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Stufenadapter mit Hahn / Tube Adapter with stopcock	011 001	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
THORACATH® Drainagekatheter zur Thoracentesis und Paracentesis	502 019E 502 020E 502 021E 502 219E 502 220E 502 221E 502 419E 502 420E 502 421E 503 019E 503 020E 503 021E 503 019EA 503 020EA 503 021EA	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
PNEUMOVENT® Ventil nach Heimlich	504 001 504 002	Class Is	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Duocath CVC Set	332 0xx	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153

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Device name or Basic UDI-DI (under MDR application)	**Article No.**	**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**
Zentralvenöses Katheter Set				TÜV NORD CERT GmbH
DUOCATH HDC Hämodialyse Katheter Set	332 01xx 332 11xx 332 21xx 342 01xx 342 11xx 342 21xx	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Einführkatheter Set	330 00xx 330 60xx 330 70xx 331 00xx 331 70xx	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
MICROSELD® PTFE Arterienkatheter Set	302 0xx 302 1xx 302 2xx 305 0xx 305 1xx 305 2xx	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
PNEUMOCATH®	503 40x 503 50x	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Quadrocath CVC Set	334 0xx	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
THORACATH®	503 0xx 503 11x	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Trilucath CVC Set	323 0xx	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
TRILUCATH HDC	323 0xx 323 1xx 323 2xx 323 3xx	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Venoseld CVC Set	331 0xx 331 1xx 331 2xx 331 3xx	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Veress-Nadel Drainage Set	503 060 503 061	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH

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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
12.07.2024	Rev0	Initial issue – based on P111F007 Rev2