TÜVNORD

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intra special catheters GmbH
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66780 Rehlingen-Siersburg
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TÜV®

Our / Your Reference	Contact	Direct Dial	Date
No.: 44 235 192153	medical@tuev-nord.de	Tel.: +49 201 825 2236	26 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 Mühlenberg Kevin Datum: 2024.07.29 15:39:45 +02'00'

(Deputy) Head of Project Management

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

TÜVNORD i. A. Digital unterschrieben von Mestmacher Bodo Datum: 2024.07.29 13:56:25 +02'00'

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:

X = Variable (Ziffer / Buchstabe) | Variable (digit / letter)

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**
PNEUMOVENT® **Ventil nach Heimlich** ***PNEUMOVENT®*** ***Valve according to Heimlich***	504 001 504 002	Class Is	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
MICROSELD® **PEBA Arterienkatheter nach Seldinger-Technik** ***MICROSELD®*** ***PEBA Arterial Catheter according to Seldinger technique***	305 0XXE 305 1XXE 305 2XXE 305 0XXEA 305 1XXEA 305 2XXEA	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
MICROSELD® **PTFE Arterienkatheter nach Seldinger-Technik** ***MICROSELD®*** ***PTFE Arterial Catheter according to Seldinger technique***	302 0XXE 302 1XXE 302 2XXE 302 0XXEA 302 1XXEA 302 2XXEA	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
NEO-PNEUMOCATH® **Drainagekatheter zur Thoracentesis und Pleurodese** ***NEO-PNEUMOCATH®*** ***Drainage Catheter for Thoracentesis and Pleurodesis***	503 011E 503 011 503 012E 503 012	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
PNEUMOCATH® **Drainagekatheter zur Thoracentesis und Pleurodese** ***PNEUMOCATH®*** ***Drainage Catheter for Thoracentesis and Pleurodesis***	503 001E 503 001 503 002E 503 002 503 003E 503 003	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Stufenadapter ***Step Adapter***	011 000	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Stufenadapter mit Drei-Wege-Hahn ***Step Adapter with Three-Way-Stopcock***	011 001	Class IIa	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH

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
THORACATH® Drainagekatheter zur Thoracentesis und Paracentesis ***THORACATH®*** ***Drainge Catheter for Thoracentesis and Paracentesis***	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
MICROSELD® PEBA Arterienkatheter Set nach Seldinger-Technik ***MICROSELD®*** ***PEBA Arterial Catheter Kit according to Seldinger technique***	305 0XX 305 1XX 305 2XX 305 0XXA 305 1XXA 305 2XXA	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
MICROSELD® PTFE Arterienkatheter Set nach Seldinger-Technik ***MICROSELD®*** ***PTFE Arterial Catheter Kit according to Seldinger technique***	302 0XX 302 1XX 302 2XX 302 0XXA 302 1XXA 302 2XXA	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
PNEUMOCATH® Drainage Set zur Thoracentesis und Pleurodese ***PNEUMOCATH®*** ***Drainage Kit for Thoracentesis and Pleurodesis***	503 401 503 401F 503 501 503 403 503 503 503 903	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
THORACATH® Drainage Set zur Thoracentesis und Paracentesis ***THORACATH®*** ***Drainge Kit for Thoracentesis and Paracentesis***	503 019 503 021 503 022 503 022V 503 025 503 119 503 019A 503 021A 503 022A 503 022VA 503 025A 503 119A	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Veress-Nadel Drainage Set zur Thoracentesis, Paracentesis und Gasinsufflation bei einer Laperoskopie	503 060 503 061	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH

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**
Veress-Needle Drainage Kit for Thoracentesis, Paracentesis and Gas Insufflation during Laperoscopy				
VENOSELD CVC Zentralvenöses Katheter Set ***VENOSELD CVC Central Venous Catheter Kit***	331 0XXH 331 0XXHN 331 0XXHNF 331 0XXHD 331 0XXHDN 331 0XXHDNY 331 0XXHR 331 0XXHRF 331 0XXHRD 331 0XXHRDF 331 0XXHF 331 0XXHDF 331 0XXHDNF 331 0XXHDNYF 331 1XXH 331 1XXHN 331 1XXHNF 331 1XXHD 331 1XXHDN 331 1XXHDNY 331 1XXHR 331 1XXHRF 331 1XXHRD 331 1XXHRDF 331 1XXHF 331 1XXHDF 331 1XXHDNF 331 1XXHDNYF 331 2XXH 331 2XXHN 331 2XXHNF 331 2XXHD 331 2XXHDN 331 2XXHDNY 331 2XXHR 331 2XXHRF 331 2XXHRD 331 2XXHRDF 331 2XXHF 331 2XXHDF 331 2XXHDNF 331 2XXHDNYF 331 3XXH 331 3XXHN 331 3XXHNF 331 3XXHD 331 3XXHDN	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH

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**
	331 3XXHDNY 331 3XXHR 331 3XXHRF 331 3XXHRD 331 3XXHRDF 331 3XXHF 331 3XXHDF 331 3XXHDNF 331 3XXHDNYF			
DUOCATH CVC Zentralvenöses Katheter Set ***DUOCATH CVC Central Venous Catheter Kit***	332 0XX 332 0XXN 332 0XXNF 332 0XXD 332 0XXDN 332 0XXDNY 332 0XXR 332 0XXRF 332 0XXRD 332 0XXRDF 332 0XXF 332 0XXDF 332 0XXDNF 332 0XXDNYF 332 0XXS 332 0XXSN 332 0XXSNF 332 0XXSD 332 0XXSDN 332 0XXSDNY 332 0XXSR 332 0XXSRF 332 0XXSRD 332 0XXSRDF 332 0XXSF 332 0XXSDF 332 0XXSDNF 332 0XXSDNYF 332 0XXS1 332 0XXS1N 332 0XXS1NF 332 0XXS1D 332 0XXS1DN 332 0XXS1DNY 332 0XXS1R 332 0XXS1RF 332 0XXS1RD 332 0XXS1RDF 332 0XXS1F 332 0XXS1DF 332 0XXS1DNF 332 0XXS1DNYF	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
TRILUCATH CVC Zentralvenöses Katheter Set	323 0XX 323 0XXN 323 0XXNF	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH

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**
TRILUCATH CVC Central Venous Catheter Kit	323 0XXD 323 0XXDN 323 0XXDNY 323 0XXR 323 0XXRF 323 0XXRD 323 0XXRDF 323 0XXF 323 0XXDF 323 0XXDNF 323 0XXDNYF 323 0XXS 323 0XXSN 323 0XXSNF 323 0XXSD 323 0XXSDN 323 0XXSDNY 323 0XXSR 323 0XXSRF 323 0XXSRD 323 0XXSRDF 323 0XXSF 323 0XXSDF 323 0XXSDNF 323 0XXSDNYF			
QUADROCATH CVC Zentralvenöses Katheter Set ***QUADROCATH CVC Central Venous Catheter Kit***	334 0XX 334 0XXN 334 0XXNF 334 0XXD 334 0XXDN 334 0XXDNY 334 0XXR 334 0XXRF 334 0XXRD 334 0XXRDF 334 0XXF 334 0XXDF 334 0XXDNF 334 0XXDNYF	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
DUOCATH HDC Hämodialyse Katheter Set ***DUOCATH HDC Hemodialysis Catheter Kit***	332 X12 332 X12N 332 X12NF 332 X12D 332 X12DN 332 X12DNY 332 X12R 332 X12RF 332 X12RD 332 X12RDF 332 X12F 332 X12DF 332 X12DNF 332 X12DNYF 332 X12C	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH

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
	332 X12P			
TRILUCATH HDC Hämodialyse Katheter Set ***TRILUCATH HDC Hemodialysis Catheter Kit***	323 X12 323 X12N 323 X12NF 323 X12D 323 X12DN 323 X12DNY 323 X12R 323 X12RF 323 X12RD 323 X12RDF 323 X12F 323 X12DF 323 X12DNF 323 X12DNYF 323 X12C 323 X12P	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 TÜV NORD CERT GmbH
Einführkatheter Set ***Introducer Catheter Kit***	331 004 331 004D 331 004I 331 004S1 331 704 331 704S1 331 704S3	Sterile Procedure Pack	N/A	93/42/EEC Annex V, No.: 44 235 192153 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
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
26.07.2024	Rev01	Corrected product list Table 1