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TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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TÜV SÜD Product Service GmbH
Confirmation Letter
CL 036993 0027 Rev. 00

Reference: 713181269

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000006938

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 TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
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  If 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93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 036993 0027 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-09

TÜV SÜD Product Service GmbH
Medical and Health Services

Bettina Hoeffeler
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Claus Matthias Mumme
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
Device 1 **4035324TWIST_PLUSSR** **TRACOE twist plus Tracheostomy Tube** **TRACOE twist plus extract Tracheostomy Tube** **TRACOE twist plus Spare Inner Cannula** **TRACOE experc Set twist plus**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate G1 036993 0016 Rev. 01 NB 0123
Device 2 **4035324TWISTX8** **TRACOE twist Tracheostomy Tube** **TRACOE twist Laryngectomy Tube** **TRACOE twist extract Tracheostomy Tube** **TRACOE twist Spare Inner Cannula** **TRACOE twist short Spare Inner Cannula** **TRACOE experc Set twist**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☐ Certification as follows: G1 036993 0016 Rev. 01 NB 0123
Device 3 **4035324VARIOT9** **TRACOE vario Tracheostomy Tube** **TRACOE vario XL Tracheostomy Tube** **TRACOE vario extract Tracheostomy Tube**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 036993 0016 Rev. 01 NB 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
TRACOE vario extract XL Tracheostomy Tube **TRACOE experc Set vario** **TRACOE experc Set vario XL**			
Device 4 **4035324SILCOSOFTEL** **TRACOE silcosoft Tracheostomy Tube** **TRACOE silcosoft PL Tracheostomy Tube**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 036993 0016 Rev. 01 NB 0123
Device 5 **4035324MINIW4** **TRACOE mini Extension Piece** **TRACOE mini Tracheostomy Tube**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 036993 0016 Rev. 01 NB 0123
Device 6 **4035324COMFORTNT** **TRACOE comfort Tracheostomy Tube** **TRACOE comfort XL Tracheostomy Tube** **TRACOE comfort plus Tracheostomy Tube** **TRACOE care Paraffin oil**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A	☒ Certification as follows: G1 036993 0016 Rev. 01 NB 0123
Device 7 **4035324AERISM6**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 036993 0016 Rev. 01 NB 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
TRACOE aeris Ballon-Dilatationskatheter	☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments		
Device 8 **4035324EXPERC_DIL_SET46** **TRACOE experc Dilation Set**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A	☒ Certification as follows: G1 036993 0016 Rev. 01 NB 0123
Device 9 **4035324COMPR_STERILE3R** **TRACOE purofaoam Tracheal Compress**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A	☒ Certification as follows: G1 036993 0016 Rev. 01 NB 0123
Device 10 **4035324SPEAK_VALVESRC** **Occlusion Cap** **Stopper** **Speaking Valves Tracoe Phone assist I**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1S 036993 0014 Rev.01 NB 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	☐ Class I reusable surgical instruments		
Device 11 **4035324SMARTTC** **TRACOE smart Cuffmanager**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A	☒ Certification as follows: G1S 036993 0014 Rev.01 NB 0123

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-04-09	713181269	Initial issue