TRACOE

Tracoe Medical GmbH | Reichelsheimer Str. 1/3 | 55268 Nieder-Olm

To whom it may concern

Tracoe Medical GmbH
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Geschäftsführer:
Dr. Hans Kränzler

Amtsgericht Mainz, HRB 44548
Steuer-Nr.: 08/658/71878

Your Reference

Our Reference

Date
May 08, 2024

Declaration of Manufacturer Stating the Fulfilment of Extension Conditions

The undersigned, acting as Managing Director of Tracoe Medical GmbH, hereby confirms that Tracoe Medical GmbH, located Reichelsheimer Str. 1/3, 55268 Nieder-Olm, Germany, has obtained an extension of the validity of its conformity assessment certificates issued by the Notified Body TÜV SÜD Product Service GmbH (NB #0123) issued under the Medical Devices Directive 93/42/CEE (MDD), in accordance with the provisions set by the Regulation EU 2023/607 amending Regulations (EU) 2017/745 (MDR).

The medical devices in scope of this extension are those listed in the Notified Body Confirmation Letter #CL 036993 0027 issued by TÜV SÜD and dated 09 April 2024.

Consistent with the provisions set out in Article 120 of the MDR, as amended, this extension entails the following conditions:

- those devices continue to comply with the MDD;
- there are no significant changes in the design and intended purpose;
- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- Tracoe Medical GmbH has put in place a quality management system in accordance with applicable provisions of the MDR;
- Tracoe Medical GmbH has lodged a formal application and has signed a mutual agreement with the Notified Body TÜV SÜD for continued surveillance under MDD and conformity assessment under the MDR, as applicable.

In accordance with the provisions set out in Article 120(3) of MDR, the transition timeline that applies to the devices manufactured by Tracoe and that are covered by this extension is 31 December 2028. Declarations of Conformity applicable to these products that were previously issued by Tracoe under the MDD remain valid up to 31 December 2028 are thereby also extended.

Declarations of Conformity issued prior to the publication of the Regulation EU 2023/607 and applicable to these devices may have been previously issued with a specified expiration date. Where such expiration date is present on the Declaration of Conformity, it should also be regarded as extended to 31 December 2028.

Attachment

- Confirmation Letter #CL 036993 0027, 7 pages.

Best regards

Dr. Hans-Marcus Kränzler
Managing Director

KONFORMITÄTSERKLÄRUNG

Entsprechend DIN EN ISO / IEC 17050-1

Die TRACOE medical GmbH, Reichelsheimer Str. 1/3, in 55268 Nieder-Olm, wendet ein Qualitätsmanagementsystem an, das den Anforderungen der DIN EN ISO 13485:2016 entspricht.
TRACOE medical GmbH erklärt in alleiniger Verantwortung, dass die folgenden Medizinprodukte allen Anforderungen der Richtlinie 93/42/EWG entsprechen, und deren Umsetzung in nationale Gesetze. Das Konformitätsverfahren gemäß Anhang II ohne (4) der Richtlinie wurde durchgeführt in Zusammenarbeit mit der Benannten Stelle:

DECLARATION OF CONFORMITY

According to DIN EN ISO / IEC 17050-1

TRACOE medical GmbH, Reichelsheimer Str. 1/3, in 55268 Nieder-Olm, Germany is maintaining a quality management system, which meets the requirements of DIN EN ISO 13485:2016.
TRACOE medical GmbH declares in its own responsibility that the following medical devices meet all requirements of the Directive 93/42/EEC and the implementation of the Directive according to national laws. The conformity assessment procedure according to Annex II excluding (4) of the Directive has been carried out in cooperation with our Notified Body:

TÜV SÜD Product Service GmbH (0123)
Ridlerstraße 65
80339 München

TRACOE *modular*

Verschlusskappe REF 516
Verschlussstopfen REF 621
22 mm Adapter REF 622

Sprechventil TRACOE phon assist I
REF 650-S, REF 650-SO, REF 650-T, REF 650-TO, REF 650-TO-5, REF 650-TO-C, REF 650-TO-C-5
Sprechventil TRACOE phon assist II
REF 655-S, REF 655-T
seit 05/1999,

Klassifizierung nach Richtlinie 93/42/EWG, Anhang IX als Medizinprodukt Klasse Is

EG-Zertifikat Nr. G1S 036993 0014 Rev. 01

Gültig bis 2024-05-26

Occlusion Cap REF 516
Stopper REF 621
22 mm Housing Adapter

Speaking valves TRACOE phon assist I
REF 650-S, REF 650-SO, REF 650-T, REF 650-TO, REF 650-TO-5, REF 650-TO-C, REF 650-TO-C-5
Speaking valves TRACOE phon assist II
REF 655-S, REF 655-T
since 05/1999,

Classification according to Directive 93/42/EEC, Annex IX, as Medical Devices, class Is

EC-Certificate No. G1S 036993 0014 Rev. 01

Valid until 2024-05-26

28.10.2021
Nieder-Olm

Rimm Elfu
General Manager

Add value.
Inspire trust.

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

TRACOE medical GmbH
Reichelsheimer Str. 1/3
55268 Nieder-Olm

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
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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.
- 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