EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

Dreve Otoplastik GmbH
Max-Planck-Straße 31
59423 Unna
Germany

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III and Class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

Single Registration Number of the Manufacturer (SRN):	DE-MF-000005459
Authorised Representative:	--
The validity of this EU Certificate depends on conditions and / or is limited to the following:	--
List of Products, Risk Classification and Details:	see Section 2
Certificate history:	see Section 3

Reg.-No.: 44 911 220476
Certification decision report No.: 3536 7641

Edition:	2
Issue date:	2024-04-22
First issued:	2023-12-05
Valid until:	2028-12-04

Essen, 2024-04-22

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
tuev-nord-cert.de
medical@tuev-nord.de

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

TÜVNORDGROUP

EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapters I and III

Reg. No. 44 911 220476 Section 2, List of Products

Class IIb (non implantable)

Product name	Intended purpose	Generic device group (EMDN)	Technical documentation assessment report number
Set for disinfection of earmolds / *Sets zur Desinfektion von Otoplastiken* Disinfectant for earmolds / *Desinfektionsmittel für Otoplastiken*	For external care and disinfection of hearing systems and earmolds / *Zur äußeren Pflege und Desinfektion von Hörsystemen und Otoplastiken*	Y214580	3533 9958

Class IIa

Product name	Category of device (MDx)	Technical documentation assessment report number
	MDN 1205	3533 9952
Addition curing ear impression silicones / *Additionsvernetzende Ohrabformsilikone* Earmold silicones / *Otoplastiksilikone* Condensation curing ear impression silicones / *Kondensationsvernetzende Ohrabformsilikone* Light-curing lacquers / *Lichthärtende Lacke* Light-curing pouring resins / *Lichthärtende Gießkunststoffe* Light-curing printing resins / *Lichthärtende Druckharze* VarioTherm Lacquers for coating silicone earmolds / *Lacke zur Beschichtung von Silikon-Otoplastiken*		

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
tuev-nord-cert.de
medical@tuev-nord.de

EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapters I and III

Reg. No. 44 911 220476 Section 3, Certificate History

Certificate History

Edition	Date	Action leading to revision	Certification decision report number
1	2023-12-05	Initial Issuance	3535 7344
2	2024-04-22	Notification Change 01 (Product extension) / Correction and amendment of English product group names	3536 7641

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
tuev-nord-cert.de
medical@tuev-nord.de