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.: 44911220476
Certification decision report No.: 35357344

Edition:	1
Issue date:	2023-12-05
First issued:	2023-12-05
Valid until:	2028-12-04

Essen, 2023-12-05

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

TÜV NORD CERT GmbH
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TÜV®

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

TÜVNORDGROUP

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

Reg. No. 44911220476 Section 2, List of Products

Class IIb (non implantable)

Product name	Intended purpose	Generic device group (EMDN)	Technical documentation assessment report number
Desinfektionsmittel für Otoplastiken	Zur äußeren Pflege und Desinfektion von Hörsystemen und Otoplastiken	Y214580	35339958

Class IIa

Product name	Category of device (MDx)	Technical documentation assessment report number
Additionsvernetzendes Ohrabformsilikon A-Silikon zur Otoplastikfertigung Kondensationsvernezende Ohrabformsilikon Lichthärtender Lack für Otoplastiken Lichthärtendes Material zur Herstellung von Otoplastiken Lichthärtendes Material zur Herstellung von Otoplastiken mittels 3D-Druck Verfahren. Ronden aus Polyurethan zum Fräsen von Otoplastiken und RIC´s mittels subtraktiven Verfahren Silikonlack zur Beschichtung von Otoplastiken und Ohrabformungen	MDN 1205	35339952

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Reg. No. 44911220476 Section 3, Certificate History

Certificate History

Edition	Date	Action leading to revision	Certification decision report number
1	2023-12-05	Initial Issuance	35357344

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