

# **EU - Declaration of Conformity for Medical Devices**

according to Annex IX Chapter I of Regulation (EU) 2017/745 on medical devices

Registration number (SRN): Manufacturer: Street: City: Country: DE-MF-000022666 DETAX GmbH Carl-Zeiss-Straße 4 76275 Ettlingen Germany

We hereby declare under our sole responsibility that the products in the Annex with the Basic UDI-DI

#### ++EDET0245L

and the classification according to Annex VIII of Regulation (EU) 2017/745

#### Class IIa, rule 5, sentence 2

and the intended use:

Earmold silicone

comply with the relevant provisions of the following EU legislation:

#### Regulation (EU) 2017/745 on medical devices

as well as the standards and common specifications:

## DIN EN ISO 15223-1:2022 DIN EN ISO 20417:2022 DIN EN ISO 10993-1:2021

#### DIN EN 62366-1:2021 DIN EN ISO 14971:2022

with the participation of the following management systems

### DIN EN ISO 13485:2021

and the conformity assessment procedure referred to in the header by the notified body: 0483

mdc medical device certification GmbH Kriegerstr. 6 D- 70191 STUTTGART

This declaration is valid until a significant change in the specification or manufacture of the product or until a change in the above-mentioned standards, common specifications, management systems and legal regulations, maximally until the expiry of the certificate with the No.:

D1002700058 in for

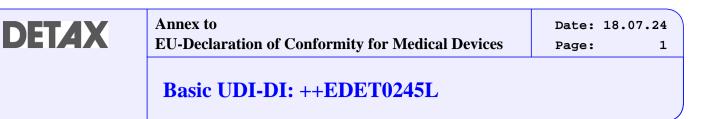
in force until 31.07.2028

Ettlingen, 18.07.2024

Thorsten Preiss Managing Director

Jack Rossing

Dr. Sönke Rössing Managing Director



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