EU - Declaration of Conformity for Medical Devices

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

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

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

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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 force until 31.07.2028

Ettlingen, 18.07.2024

Thorsten Preiss
Managing Director

Dr. Sönke Rössing
Managing Director

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