

EU Registrierungsnummer SRN

DE-MF-000022666

Manufacturer:

detax GmbH

Street:

Carl-Zeiss-Str. 4

Location:

76275 Ettlingen

Country:

Germany

We hereby declare under our sole responsibility that the products in the appendix with the basis UDI-DI

++EDET0866A

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

Class IIa, rule 5, sentence 1, 3rd indent

and the intended purpose:

Surface finish for earmolds or silicone impressions

complies with the relevant provisions of the following EU legislation:

Regulation (EU) 2017/745

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 procedure for conformity assessment by the notified body mentioned in the header:

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.:

D1002700059 31/07/2028

Ettlingen, 03.07.25



Thorsten Preiss

Geschäftsführer



Dr. Sönke Rössing

Geschäftsführer

detax	Annex to the EU declaration of conformity for medical devices	Date: 03/07/25
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