

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

**++EDET0265Q**

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

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

and the intended purpose:

**UV varnish for 3D-printed earmolds**

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, 14.07.25



Thorsten Preiss

Geschäftsführer



Dr. Sönke Rössing

Geschäftsführer

detax	Annex to the EU declaration of conformity for medical devices	Date: 14/07/25
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<div><div>+EDET035941</div><div>luxaprint shellac 100 ml</div></div> <div><div>+EDET035951</div><div>luxaprint shellac 300 ml</div></div> <div><div>+EDET035961</div><div>luxaprint shellac Muster 5ml</div></div> <div><div>+EDET040061</div><div>luxaprint shellac 50 ml</div></div>		
		