

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

++EDET0815Y

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

Class IIa, rule 19, sentence 1, 3rd indent

and the intended purpose:

Plastic material for the production of ITE shells in 3D printing processes

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, 01.07.25



Thorsten Preiss

Geschäftsführer



Dr. Sönke Rössing

Geschäftsführer

detax	Annex to the EU declaration of conformity for medical devices	Date: 01/07/25
	Basic-UDI ++EDET0815Y	Page: 1
+EDET030161 medicalprint shell beige 2.0 1.000 g 		

detax	Annex to the EU declaration of conformity for medical devices	Date: 01/07/25
	Basic-UDI ++EDET0815Y	Page: 1
+EDET021921 medicalprint shell skin 2.0 1.000 g 		

detax	Annex to the EU declaration of conformity for medical devices	Date: 01/07/25
	Basic-UDI ++EDET0815Y	Page: 1
+EDET030431 medicalprint shell schwarz 1.000 g 		

detax	Annex to the EU declaration of conformity for medical devices	Date: 01/07/25
	Basic-UDI ++EDET0815Y	Page: 1
+EDET040731 medicalprint shell weiß 1.000 g 		

detax	Annex to the EU declaration of conformity for medical devices	Date: 01/07/25
	Basic-UDI ++EDET0815Y	Page: 1
+EDET041641 medicalprint shell blau-opak 1.000 g 		

detax	Annex to the EU declaration of conformity for medical devices	Date: 01/07/25
	Basic-UDI ++EDET0815Y	Page: 1
+EDET041651 medicalprint shell rot-opak 1.000 g 		