

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

**++EDET1095V**

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

**Class IIa, rule 5, sentence 2**

and the intended purpose:

**Resin material for the production of earmolds and 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, 17.07.25



Thorsten Preiss

Geschäftsführer



Dr. Sönke Rössing

Geschäftsführer


**Basic-UDI**


**++EDET1095V**


+EDET045561


Medicalprint nobreak beige 1000 g




detax	Annex to the EU declaration of conformity for medical devices	Date: 17/07/25
	Basic-UDI ++EDET1095V	Page: 1
<div>+EDET045571</div> <div>Medicalprint nobreak black 1000g</div> <div></div>		

detax	Annex to the EU declaration of conformity for medical devices	Date: 17/07/25
	Basic-UDI ++EDET1095V	Page: 1
<div>+EDET045591</div> <div>Medicalprint nobreak brown 1000g</div> <div></div>		


detax	Annex to the EU declaration of conformity for medical devices	Date: 17/07/25
	Basic-UDI ++EDET1095V	Page: 1
<div>+EDET045621</div> <div>Medicalprint nobreak dark brown 1000g</div> <div></div>		

detax	Annex to the EU declaration of conformity for medical devices	Date: 17/07/25
	Basic-UDI ++EDET1095V	Page: 1
<div>+EDET045631</div> <div>Medicalprint nobreak dark grey 1000g</div> <div></div>		

detax	Annex to the EU declaration of conformity for medical devices	Date: 17/07/25
	Basic-UDI ++EDET1095V	Page: 1
<div>+EDET045641</div> <div>Medicalprint nobreak green-opaque 1000g</div> <div>CE</div>		

detax	Annex to the EU declaration of conformity for medical devices	Date: 17/07/25
	Basic-UDI ++EDET1095V	Page: 1
<div>+EDET045661</div> <div>Medicalprint nobreak light grey 1000g</div> <div></div>		



detax	Annex to the EU declaration of conformity for medical devices	Date: 17/07/25
	Basic-UDI ++EDET1095V	Page: 1
<div>+EDET045671</div> <div>Medicalprint nobreak medium brown 1000g</div> <div></div>		


**Basic-UDI**

**++EDET1095V**

+EDET045731

Medicalprint nobreak skin 1000g



detax	Annex to the EU declaration of conformity for medical devices	Date: 17/07/25
	Basic-UDI ++EDET1095V	Page: 1
<div>+EDET045741</div> <div>Medicalprint nobreak white 1000g</div> <div></div>		