

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

++EDET1055M

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


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<div>+EDET045601</div> <div>Medicalprint nobreak clear 1000g</div> <div>CE</div>		

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<div>+EDET045581</div> <div>Medicalprint nobreak blue-transp 1000g</div> <div></div>		

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<div>+EDET045651</div> <div>Medicalprint nobreak light beige 1000g</div> <div></div>		

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<div>+EDET045681</div> <div>Medicalprint nobreak neon yellow 1000g</div> <div></div>		

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<div>+EDET045691</div> <div>Medicalprint nobreak purple 1000g</div> <div></div>		

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<div>+EDET045701</div> <div>Medicalprint nobreak red-transp 1000g</div> <div></div>		

Basic-UDI

++EDET1055M

+EDET045711

Medicalprint nobreak rose 1000g



+EDET045721

Medicalprint nobreak rose-orange 1000g



Basic-UDI

++EDET1055M

+EDET046311

Medicalprint nobreak orange-transp 1000g

