

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

**++EDET0255N**

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, 01.07.25



Thorsten Preiss

Geschäftsführer





Dr. Sönke Rössing


Geschäftsführer

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Basic-UDI ++EDET0255N		
<div><div>+EDET033161</div><div>medicalp. mould clear 2.0 EcoBag 5kg</div></div> <div><div>+EDET042241</div><div>medicalprint mould clear 2.0 1.000 g</div></div> <div><div>+EDET043411</div><div>medicalp. mould clear 2.0 EcoBag 3kg</div></div>		
<div><div>CE</div></div>		

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Basic-UDI ++EDET0255N		
<div><div>+EDET024491</div><div>medicalprint mould rose 2.0 1.000 g</div></div> <div><div>+EDET033141</div><div>medicalprint mould rose 2.0 EcoBag 5 kg</div></div> <div><div>+EDET043421</div><div>medicalprint mould rose 2.0 EcoBag 3 kg</div></div>		
<div><div></div><div>CE</div><div></div></div>		

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Basic-UDI ++EDET0255N											
<table><tr><td>+EDET029031</td><td>medicalprint mould rose-orange 2.0 500 g</td></tr><tr><td>+EDET029041</td><td>medicalprint mould rose-orange 2.0 1000g</td></tr><tr><td>+EDET033041</td><td>medicalp. mould rose-or. 2.0 EcoBag 5 kg</td></tr><tr><td>+EDET043431</td><td>medicalp. mould rose-or. 2.0 EcoBag 3 kg</td></tr></table>				+EDET029031	medicalprint mould rose-orange 2.0 500 g	+EDET029041	medicalprint mould rose-orange 2.0 1000g	+EDET033041	medicalp. mould rose-or. 2.0 EcoBag 5 kg	+EDET043431	medicalp. mould rose-or. 2.0 EcoBag 3 kg
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<div>+EDET040161</div> <div>MedicalPrint mould clear 1.000 g</div> <div></div>		

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<div>+EDET040881                      medicalprint mould rosé 1.000 g</div> <div></div>		