

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

++EDET0465W

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

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

and the intended purpose:

Composite for dental 3D printing

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 14971:2022 DIN EN ISO 7405:2019 DIN EN ISO 10993-1:2021 DIN EN 62366-1:2021

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

Basic-UDI ++EDET0465W

+EDET020761 freeprint splint 2.0 385 1.000 g

+EDET020801 freeprint splint 2.0 385 500 g

