EC-Declaration of Conformity

Declaration of Conformity according to Regulation (EU) 2017/745 – Medical devices

We, the company

retec® Kunststofftechnik GmbH
Industriestraße 2
D-61191 Rosbach v.d.Höhe (Rodheim)

SRN: DEMF000000086

hereby declare in full responsibility as designer, manufacturer and first supplier, that the medical device group

SHERATRAY

Basic UDI-DI: ++D945TRAYJQ

Non-stick dental resin. Autopolymer based on methyl-methacrylate in form of powder and liquid. For manufacturing of individual impression trays.

Class I
classification according to Regulation (EU) 2017/745, annex VIII, section III, rule 5, first mirror line

according to Annex I of Regulation (EU) 2017/745 meet all applicable general safety and performance requirements.

Applied conformity assesement procedure:	Regulation (EU) 2017/745, Annex IV
Applied common specifications:	-

This EC-Declaration of Conformity is valid until: **December 31th 2028**

Rosbach, 03.06.2024

Dr. Manfred Steinbach
PRRC (Person responsible for regulatory compliance)
retec® Kunststofftechnik GmbH

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Productlist „Acrylics for the manufacturing of individual impression trays “

Artikel-No.	Product name
SHE-505010	SHERATRAY impression trays; powder 1000 g - blue opak
SHE-505050	SHERATRAY impression trays; powder 1000 g - white opak
SHE-505060	SHERATRAY impression trays; powder 1000 g - pink opak
SHE-508080	liquid für SHERATRAY; liquid - 500 ml

Produktliste „Kunststoffe zur Herstellung von individuellen Abformlöffeln“

Artikel-Nr.	Produktname
SHE-505010	SHERATRAY Löffelmaterial; Pulver 1000 g - blau opak
SHE-505050	SHERATRAY Löffelmaterial; Pulver 1000 g - weiß opak
SHE-505060	SHERATRAY Löffelmaterial; Pulver 1000 g - rosa opak
SHE-508080	FLÜSSIGKEIT für SHERATRAY; Flüssigkeit - 500 ml