EC-Declaration of Conformity

We, the company

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

hereby declare in full responsibility as designer, manufacturer and first supplier, that the quality and safety relevant properties of our product variant from the medical device

“Acrylics for the manufacturing of orthodontic appliances”

SHERAORTHOMER

(including all color variations)

classification according to 93/42/EEC annex IX, section III, rule 5 (duration of use > 30 days):

Class IIa

fulfill the following fundamental requirements:

Directive 93/42/CEE concerning medical devices - Annex II

Notified Body: **DQS Medizinprodukte GmbH**, August-Schanz-Straße 21, 60433 Frankfurt am Main, CE 0297

Certificate Registration No.: 059034 MR2

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

Rosbach, 17.05.2024

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

Productlist „Acrylics for the manufacturing of orthodontic appliances“

Artikel-N0.	**Product name**
SHE-504010	SHERAORTHOMER; powder, 1000 g, transparent
SHE-508050	liquid for SHERAORTHOMER; 500 ml