3M

EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Deutschland GmbH
Health Care Business
Single Registration Number: DE-MF-000012859
Carl-Schurz-Str. 1
41453 Neuss
Germany

hereby declare under our sole responsibility that the following CE marked device(s)

Trade Name	RelyX U200
Intended Purpose	Dental luting agent for cementation of indirect restorations
Reference	56877, 56878, 56879 (mixing pad included as part of the device)
Basic UDI-DI	0608223276102000000023DN

is/are classified per rules 8 and 19 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class IIa device(s) in accordance with Annex IX and all other applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

This declaration is made based on the quality assurance certificate
EU QMS Certificate (MDR): G10 078535 0040
Issued by: TÜV SÜD Product Service GmbH (identification no. 0123)

Dr. Desi W. Soegiarto
Manager Regulatory Medical Devices
3M Deutschland GmbH

Seefeld/December 15, 2022
Location/Date