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	Impregum Soft
Intended Purpose	Dental impression material
Reference	31475, 31749, 31750, 31755 (mixing block partially included as part of the device)
Basic UDI-DI	06082232761020000000005DL

is/are classified per rules 4 and 19 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class IIa devices 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, October 06, 2021
Date