3M

EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Deutschland GmbH
Health Care Business
Single Registration Number: *has not yet been issued by competent authority*
Carl-Schurz-Str. 1
41453 Neuss
Germany

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

Trade Name	Astringent Retraction Paste
Intended Purpose	Astringent paste for temporary displacement of the marginal gingiva and for hemostasis and moisture control.
Reference	56943, 56944, 56945 As part of system/procedure pack(s): 69381, 69383, 69407, 69413, 69414, 69415
Basic UDI-DI	06082327610200000000001DC

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

July 24, 2020
Date