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	Pentamix Lite
Intended Purpose	Dental impression material mixer
Reference	77901, 77902, 77903, 77904, 77905, 77906, 77907, 77908, 77909, 78000 *Penta Cartridge for Pentamix Lite*: 77944
Basic UDI-DI	06082232761020000000095EF

is/are classified per rule 13 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

We hereby declare under our sole responsibility that the following CE marked accessory(ies) which are intended to be used together with the above medical device(s)

Accessory(ies)	Reference	Basic UDI-DI	Rule(s) of Annex VIII	Class
Penta Mixing Tips – Red	77919, 77949	06082232761020000000094ED	1	I

is/are classified according to Annex VIII of the Medical Device Regulation (EU) 2017/745 in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

3M Deutschland GmbH self-declares conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and compliance to the requirements of EN IEC 63000:2018.

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

Seefeld/September 28, 2022
Location/Date