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 Penta Super Quick Impregum Super Quick
Intended Purpose	Dental impression material
Reference	69379, 69380, 69382, 69384, 69385, 69386, 69404, 69405, 69406, 69410, 69411, 69412, 69416, 69417, 69418, 69419, 69421
Basic UDI-DI	06082232761020000000005DL

is/are classified per rule 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.

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
Pentamix 3	77871, 77872, 77873, 77874, 77875, 77876, 77878	0608223276102 0000000095EF	13	I
Including its components: Penta Cartridge for Pentamix 3	69387, 69401	0608223276102 0000000095EF	13	I
Penta Universal Cartridge for Pentamix 3	71545	0608223276102 0000000095EF	13	I
Pentamix Lite	77901, 77902, 77903, 77904, 77905, 77906, 77907, 77908, 77909, 78000	0608223276102 0000000095EF	13	I

Accessory*(ies)*	Reference	Basic UDI-DI	Rule*(s)* of Annex VIII	Class
Including its component: Penta Cartridge for Pentamix Lite	77944	0608223276102 0000000095EF	13	I
Penta Mixing Tips – Red	77919, 77949	0608223276102 0000000094ED	1	I
Penta Elastomer Syringe	71210	0608223276102 0000000093EB	5	I
Intra-Oral Tips for Penta Elastomer Syringe / Elastomer Syringe	71225	0608223276102 0000000092E9	5	I
Garant Dispenser 1:1/2:1	77580	0608223276102 0000000015DP	1	I
Garant Mixing Tip - Purple	71454	0608223276102 0000000016DR	5	I
Garant Intraoral Tip - White	71461N	0608223276102 0000000017DT	5	I
Intra-oral Syringe – Purple	71507, 71508	0608223276102 0000000010DD	5	I
Polyether Adhesive	30600	0608223276102 0000000003DG	5	I
Polyether Contact Tray Adhesive	69408, 69409	0608223276102 0000000002DE	5	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.

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)

3M Deutschland GmbH self-declares conformity of Pentamix 3 and Pentamix Lite 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, March 18, 2022
Location/Date