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
Intended Purpose	Dental impression material
Reference	31644, 31791, 31793, P31684
Basic UDI-DI	06082327610200000000005DL

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.

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	P3792	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
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
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 9, 2022
Location/Date