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	Ketac Cem Aplicap
Intended Purpose	dental luting agent for cementation of indirect restorations and orthodontic bands
Reference	56060, 56061
Basic UDI-DI	06082327610200000000044DW

is/are classified per rules 8 and 19 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class IIa device(s) 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
Aplicap Activator	73040	0608223276102000000091E7	1	I
Aplicap Applier	73050	0608223276102000000090E5	5	I
Aplicap Activator & Applier	37160	0608223276102000000086EE	1, 5	I
CapMix	76190, 76191, 76193, 76195	0608223276102000000013DK	13	I
RotoMix	76300, 76301, 76303, 76304, 76305, 76310	0608223276102000000014DM	13	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 CapMix and RotoMix 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/November 11, 2022
Location/Date