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	Photac Fil Quick Aplicap
Intended Purpose	Glass ionomer based dental restorative
Reference	61010, 61012, 61020, 61030, 61040, 61050, 61060, 61070, 61080, 61082, 61083, 61084, 61090
Basic UDI-DI	06082327610200000000026DU

is/are classified per rules 8 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
Aplicap Activator	73040	0608223276 1020000000 091E7	1	I
Aplicap Applier	73050	06082232761 02000000009 0E5	5	I
Aplicap Activator & Applier	37160	06082232761 02000000008 6EE	Activator: 1 Applier: 5	I

is/are classified according 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)

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

July 15, 2021
Date