



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	Garant Dispenser 1:1/2:1
Intended Purpose	Mixing and application device for dental impression and temporization material in cartridges.
Reference	77580 as part of system/procedure pack(s): P31772, P31738
Basic UDI-DI	06082232761020000000015DP

is/are classified per rule 1 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
Garant Mixing Tip - Green	71450	06082232761 0200000000 16DR	5	I
Garant Mixing Tip - Purple	71454	06082232761 0200000000 16DR	5	I
Garant Mixing Tip - White	71451	06082232761 0200000000 16DR	5	I
Garant Mixing Tip - Yellow	71452	06082232761 0200000000 16DR	5	I
Garant Intraoral Tip - Bite	71460	06082232761 0200000000 17DT	5	I
Garant Intraoral Tip - White	71461N	06082232761 0200000000 17DT	5	I
Garant Intraoral Tip - Yellow	71462	06082232761 0200000000 17DT	5	I

Garant Mixing Tip – Green, Garant Mixing Tip – Purple, Garant Mixing Tip – White, Garant Mixing Tip – Yellow, Garant Intraoral Tip – Bite, Garant Intraoral Tip – White, Garant Intraoral Tip – Yellow as part of various system/procedure pack(s)

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.

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

July 1, 2020
Date