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EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

Solventum Germany GmbH
Edisonstrasse 6
59174 Kamen, Germany
Single Registration Number: DE-MF-000038373

hereby declare under our sole responsibility that the following CE marked device(s)

Trade Name	Solventum Protemp 4
Intended Purpose	Temporary restorative material for temporary restoration on prepared teeth
Reference	46953, 46954, 46956, 46957, 46959, 46960, 46972
Basic UDI-DI	01979982761020000000040QX

is/are classified per rule 8 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class IIa device and is in conformity with 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)	Solventum Garant Mixing Tips - Blue
Intended Purpose	Accessories intended to be used together with dental pastes to specifically enable the medical devices to be used in accordance with their intended purposes
Reference	71453
Basic UDI-DI	01979982761020000000016R2
Rule(s) of Annex VIII	Rule 5
Class	I

is/are classified per rule 5 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I device and is in conformity with all other applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

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For Class IIa devices, this declaration is made based on the quality assurance certificate.
EU QMS Certificate (MDR): G15 123666 0006
Issued by: TÜV SÜD Product Service GmbH (identification no. 0123)
Conformity assessment procedure: According to Chapter I and III of Annex IX of the Medical Device Regulation (EU) 2017/745.

Dr. Desi W. Soegiarto
Principal Regulatory Affairs Specialist
Dental Solutions

Seefeld/November 7, 2025
Location/Date