solventum

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

Trade Name	Solventum Filtek Composite Warmer
Intended Purpose	Warming device for Filtek composites in capsules and flowable syringes used in dentistry.
Reference	6520K, 6520H, 6520S
Basic UDI-DI	01979982761020000000031QW

is classified per rule 13 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I device in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

Solventum Germany GmbH self-declares conformity 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
Principal Regulatory Affairs Specialist
Dental Solutions

Seefeld, July 22, 2025
Location/Date