

EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Deutschland GmbH Health Care Business Single Registration Number: DE-MF-000011641 Carl-Schurz-Str. 1 41453 Neuss Germany

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

Trade Name*	Adaptic [™] Touch Non-Adhering Silicone Dressing
Intended Purpose	Adaptic [™] Touch Non-Adhering Silicone Dressing is indicated for use in the management of dry to heavily exuding, partial and full-thickness chronic wounds including venous ulcers, decubitus (pressure) ulcers and diabetic ulcers, and for traumatic and surgical wounds, donor sites and 1st and 2nd degree burns. It is also suitable for use, under medical supervision, with negative pressure wound therapy (NPWT).
Reference	TCH501, TCH502, TCH 503, TCH 504, TCH501D, TCH502D, TCH 502D120, TCH 503D, TCH502F, TCH 503F, TCH 504F
Basic UDI-DI	06082238401010000000194B2

are classified per rule 4 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class IIb 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.

This declaration is made based on the quality assurance certificate EC Certificate Number: 003626MDR2017Q Issued by: DQS Medizinprodukte GmbH, No. 0297

Margaret Bessenbach

Margaret Bessenbach Director Regulatory Affairs and Quality Health Care Business EMEA 3M Deutschland GmbH October 10, 2022

Date

3M is a trademark of 3M.