

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 devices

Trade Name	3M™ Adaptic™ Digit
Intended	Non-Adhering Digit Dressing
Purpose	
Reference	MAD003, MAD013, MAD023, MAD042, MAD062
	315931, 315932, 315933 (for France only)
	MAD013D, MAD023D, MAD062D (for German only)
Basic UDI-DI	06082238401010000000202A8

are classified per rule 4 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class 1 sterile 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 EU Quality Management Certificate: 003626MDR2017Q Issued by: DQS Medizinprodukte GmbH, No. 0297

Margaret Bessenbach

October 10, 2022

Date

Director Regulatory Affairs and Quality
Health Care Business EMEA
3M Deutschland GmbH

3M is a trademark of 3M.

Related to REG-STED-MDR-05-763511