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™ Kerramax Care™ Super-Absorbent Dressing
Intended Purpose	Kerramax Care™ Dressing is a single use, sterile, non-invasive medical device, intended for short term use (30 days cumulative) in the management of moderate to highly exuding wounds, which have breached the dermis on injured skin and can only heal by secondary intent. Kerramax Care™ Dressing has a high absorption and retention capacity of fluid, helping to reduce peri-wound maceration.
Reference	PRD500-025, PRD500-025-B550, PRD500-050, PRD500-050-B50, PRD500-050-B550, PRD500-065, PRD500-100, PRD500-100-B550, PRD500-120, PRD500-120-B50, PRD500-240, PRD500-240-B30, PRD500-380-B10, PRD500-380-B30, PRD500-600-B10
Basic UDI-DI	06082238401010000000198BA

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 certificate.
EU Quality Management Certificate: 003626MDR2017Q
Issued by: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany No. 0297

Neuss, July 26, 2023

Harald Ceschinski
Manager Regulatory Affairs and
Quality Management System
Health Care Business EMEA
3M Deutschland GmbH

Location/Date