



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	3M™ Opticlude™ 3M™ Opticlude™ Standard
Intended Purpose	Orthoptic Eye Patch for occlusion therapy
Reference	1537T, 1537/20, 1537/50, 1537M-100, 1537M-50, 2537PE, 2537PF, 1537/100, 2537M D PB-100, 2537M D PG-100, 1538M – 100, 1538M-50, 2538PE, 2538M D PB-50, 2538M D PG-50, 1539T, 1539/20, 1539 / 50, 1539M – 100, 1539M-50, 2539PE, 2539PF, 1539/100. 2538M D PB-100, 2538M D PG-100, 2539M D PB-100, 2539M D PG-100
Basic UDI-DI	06082232761010000000021CK

are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I non-sterile devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

December 2, 2022

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

Date

3M is a trademark of 3M

Related to REG-STED-MDR-05-524776