EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss
Germany

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

Trade Name	Scotchcast™ Soft Cast
Intended Purpose	Scotchcast™ Soft Cast is intended to construct casts for management of fractures as well as specialized prosthetics and orthotic devices. It can also be used for the following specific applications: • orthopedic/trauma cast applications in a so called “Functional Stabilization” in fracture management, • specialized pediatric indications, for serial casting in neuro-spastic patients, prosthetics and orthotic devices • in the so called “Total Contact Cast” applications in diabetic foot ulcer treatment. Suitability of the device for the particular application is the responsibility of a qualified, on-site medical professional.
Reference	82101, 82102, 82103, 82104, 82105, 82101R, 82102R, 82103R, 82104R, 82101B, 82102B, 82103B, 82104B, 82101U, 82102U, 82103U, 82104U, 82102A, 82103A, 82102X, 82103X
Basic UDI-DI	06082327610100000000028CZ

are classified per rule 1 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.

Margaret Bessenbach

June 03, 2020
Date

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