

Status: Release Release Date: 06/03/2020

## EUROPEAN MEDICAL DEVICE REGULATION

## **Declaration of Conformity**

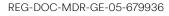
As Legal Manufacturer, we

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	06082232761010000000028CZ

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





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## REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

Margaret Bessenbach
Manager Regulatory Affairs and Quality
Health Care Business EMEA

June 03, 2020

Date

3M is a trademark of 3M.

3M Deutschland GmbH