EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company
Single Registration Number: US-MF-000014086
2510 Conway Ave. St. Paul, MN 55144 USA

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

Trade Name	Steri-Drape™ Incise Drape Steri-Drape™ 2 Incise Drape
Accessories	Not applicable.
Intended Purpose	Steri-Drape™ and Steri-Drape™ 2 Incise Drapes are indicated for use as incise drapes to cover patient's skin. They are intended for external use only.
Reference	1035, 1040, 1050, 1051 2040, 2045, 2050, 2051
Basic UDI-DI	06082238401010000000073AM

are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class Is devices in accordance with all 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
EC Certificate Number: MDR 725202
Issued by: British Standards Institute, 2797

The Authorized European Representative for the concerned devices is

3M Deutschland GmbH
Health Care Business
Single Registration Number: DE-AR-000011642
Carl-Schurz-Str. 1
41453 Neuss, Germany

Dianne Gibbs, Division Regulatory Affairs Director
3M Company
2510 Conway Ave. St. Paul, MN 55144 USA

27 January 2022
Date

3M and Steri-Drape are trademarks of 3M.