

**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)*

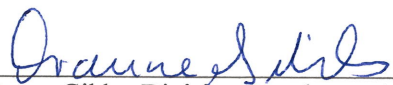
Trade Name	Steri-Drape™ Incise Drape Steri-Drape™ 2 Incise Drape
Accessories	Not applicable.
Intended Purpose	Steri-Drape™ and Steri-Drape™ 2 Incise Drapes are indicated for use as incise drapes to cover patient's skin. They are intended for external use only.
Reference	1035, 1040, 1050, 1051 2040, 2045,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

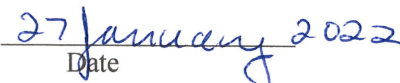
are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class Is devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

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

  
\_\_\_\_\_  
Date

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