EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company

Single Registration Number *(TBD)*
2510 Conway Ave. St. Paul, MN 55144 USA

hereby declare under our sole responsibility that the following CE marked devices

Trade Name	1. 3M™ Single-Patient Stethoscope 2. 3M™ Pediatric Single-Patient Stethoscope
Intended Purpose	Mechanical Stethoscope
Reference	1. SPS-YA1010, SPS-YA1100 2. SPS-YP1010, SPS-YP1100
Basic UDI-DI	1. 06082238401010000000037AH 2. 06082238401010000000038AK

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

The Authorized European Representative for the concerned devices is

3M Deutschland GmbH
Health Care Business
Single Registration Number (TBD)
Carl-Schurz-Str. 1
41453 Neuss, Germany

Dianne Gibbs

4 August 2020
Date

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

Issued to Authorized Representative (EC REP)

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