

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. 0608223840101000000037AH
	2. 0608223840101000000038AK

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

Division Regulatory Affairs Manager

3M Company

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3M is a trademark of 3M.