EUROPEAN MEDICAL DEVICE REGULATION

Statement

As System Producer, we

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

hereby declare that

the following systems

Name of system	3M Littmann CORE Stethoscope System
Reference	8490, 8572, 8863, 8869
Basic UDI-DI	06082238401010000000055AK

containing the following products

Product	**Reference**	**Basic UDI-DI**	**Rule of Annex VIII**	**Class**
3M™ Littmann® Cardiology IV™ Stethoscope	6000 series	060822384010 10000000026AC	1	I

and

Product	**Reference**	**Basic UDI-DI**	**Rule of Annex IX (MDD)**	**Class**
Eko CORE Model E6 System	E6	N/A	10	IIa

are classified according to Article 22 p.1 of the Medical Device Regulation (EU) 2017/745 as a system

and that

- all medical-devices included in the above system/procedure pack are CE marked;
- the mutual compatibility of the medical devices in accordance with the manufacturer's instructions (in specific regarding the products' intended purpose and specified limits of use) has been verified and the activities related

to combining them have been carried out in accordance with those instructions;

- 3M Company packages the system or procedure pack;
- relevant information is supplied to users incorporating information to be supplied by the manufacturers of the medical devices which have been put together;
- the activity of combining medical devices as a system or procedure pack is subject to appropriate methods of internal monitoring, verification, and validation.

Dianne L. Gibbs

27 January 2022

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

Date