	<b>Statement per Article 22 EU Medical Device Regulation</b>	Page 1 of 2
		Name: REG-MDR-ART22-US-05-683369 Revision: 3 State: Review Release Date: <<Release Date>>
<b>Title:</b> EU MDR Article 22 Declaration for 3M Littmann CORE Stethoscope System		

**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	Ila

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

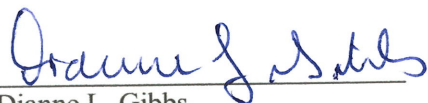
and that

- 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

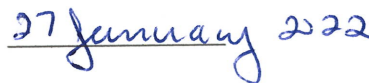
	<p align="center"><b>Statement per Article 22 EU Medical Device Regulation</b></p>	<p align="right">Page 2 of 2 Name: REG-MDR-ART22-US-05-683369 Revision: 3 State: Review Release Date: &lt;&lt;Release Date&gt;&gt;</p>
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to combining them have been carried 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  
Regulatory Affairs Director  
3M Company  
2510 Conway Ave.  
St. Paul, MN 55144 USA



Date

3M, Littmann, and Cardiology IV are marks and/or registered marks of 3M.