

	<b>Statement per Article 22 EU Medical Device Regulation</b>	Page 1 of 2 Name: REG-MDR-ART22-US-05-683369 Revision: 4 State: Release Release Date: 08/16/2022 04:27:48 PM CDT
		<b>Title: EU MDR Article 22 Declaration for 3M Littmann CORE Stethoscope System</b>

## **EUROPEAN MEDICAL DEVICE REGULATION**

### **Statement**

As System Producer, we

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


and

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

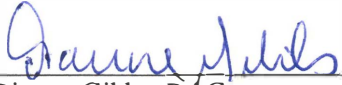
are classified according to Article 22 p.1 of the Medical Device Regulation (EU) 2017/745 as a system

and that

- all medical-devices included in the above system 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.

	<b>Statement per <i>Article 22</i></b> <b>EU Medical Device Regulation</b>	Page 2 of 2 Name: REG-MDR-ART22-US-05-683369 Revision: 4 State: Release Release Date: 08/16/2022 04:27:48 PM CDT
<b>Title:</b> EU MDR Article 22 Declaration for 3M Littmann CORE Stethoscope System		

- 3M Company packages the system.
- 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 is subject to appropriate methods of internal monitoring, verification, and validation.

  
Dianne Gibbs, RAC  
Regulatory Affairs Director  
3M Medical Solutions Division

17 August 2022  
Date

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

## DECLARATION OF CONFORMITY

We hereby declare that the products identified below are in conformity with all relevant provisions of Council Directive 93/42/EEC, (2007/47/EC as amended September 21, 2007 (M5)), concerning Medical Devices. Conformity to Directive 93/42/EEC is assessed by the notified body, Eurofins Expert Services Oy. This Declaration of Conformity is made under Annex II, section 3 of this directive.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, meet the provisions of the EC-Directive, which apply to them, including an EC Authorized Representative. The Authorized Representative is Emergo Europe, located at Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

We ensure and declare that the distributed products, as mentioned and falling within Class IIa, meet the provisions of ISO 13485 under CMDR (Health Canada). Eko Devices will serve as the Canadian regulatory correspondent.

This declaration is based on the application of the Quality System approved for the design, manufacture, and distribution of the products concerned, in accordance with Annex II (section 3, Full Quality Assurance System) of Directive 93/42/EEC. This declaration is supported by the Quality System certification based on the harmonized standards EN ISO 13485:2016, certificate number EUFI29-21000179-S (expiration date: 18th December 2024), EC Certificate No. C-01-1189-729-20 (expiration date: 27th May 2024) and MDSAP certificate number 528011 MDSAP16 (Certificate Unique ID: 170776911; expiration date: 17th December 2022).

Notified Body:

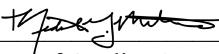
Eurofins Expert Services Oy  
Notified Body No. 0537  
Kivimiehentie 4  
02150 Espoo  
Finland

This Declaration of Conformity covers and concerns the following products:

- **Eko Analysis Software (EAS)**

This Declaration of Conformity is valid for all products described here above, bearing the CE marking and manufactured at the following site(s):

Eko Devices, Inc.  
1212 Broadway, Suite 100  
Oakland, CA 94612  
USA

Authorized Signatory:  Date: 28JUL2022  
Nicholas Metrakos, Director of Quality Assurance



## DECLARATION OF CONFORMITY

We hereby declare that the products identified below are in conformity with all relevant provisions of Council Directive 93/42/EEC, (2007/47/EC as amended September 21, 2007 (M5)), concerning Medical Devices. Conformity to Directive 93/42/EEC is assessed by the notified body, Eurofins Expert Services Oy. This Declaration of Conformity is made under Annex II, section 3 of this directive.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, meet the provisions of the EC-Directive, which apply to them, including an EC Authorized Representative. The Authorized Representative is Emergo Europe, located at Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

We ensure and declare that the distributed products, as mentioned and falling within Class IIa, Rule 10, meet the provisions of ISO 13485 under CMDR (Health Canada). Eko Devices will serve as the Canadian regulatory correspondent.

This declaration is based on the application of the Quality System approved for the design, manufacture, and distribution of the products concerned, in accordance with Annex II (section 3, Full Quality Assurance System) of Directive 93/42/EEC. This declaration is supported by the Quality System certification based on the harmonized standards EN ISO 13485:2016, certificate number EUFI29-21000179-S (expiration date: 18th December 2024), EC Certificate No. C-01-1189-729-20 (expiration date: 27th May 2024) and MDSAP certificate number 528011 MDSAP16 (Certificate Unique ID: 170776911; expiration date: 17th December 2022).

Notified Body:  
Eurofins Expert Services Oy  
Notified Body No. 0537  
Kivimiehentie 4  
02150 Espoo  
Finland

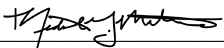
This Declaration of Conformity covers and concerns the following products:

- **Eko CORE (Eko CORE Digital Stethoscope)**
- **Eko CORE Digital Attachment**

This Declaration of Conformity is valid for all products described here above, bearing the CE marking and manufactured at the following site(s):

# Eko

Eko Devices, Inc.  
1212 Broadway, Suite 100  
Oakland, CA 94612  
USA

Authorized Signatory:  Date: 15JUL2022  
Nicholas Metrakos, Director of Quality Assurance



## 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	<ol style="list-style-type: none"><li>1. Littmann® Cardiology IV™ Stethoscope</li><li>2. Littmann® Classic III™ Stethoscope</li><li>3. Littmann® Classic II Pediatric Stethoscope</li><li>4. Littmann® Master Cardiology™ Stethoscope</li><li>5. Littmann® Master Classic II™ Stethoscope</li><li>6. Littmann® Classic II SE Stethoscope</li><li>7. Littmann® Classic II Infant Stethoscope</li><li>8. Littmann® Lightweight II SE Stethoscope</li></ol>
Intended Purpose	Stethoscope
Reference	<ol style="list-style-type: none"><li>1. 6151, 6152, 6154, 6155, 6156, 6158, 6159, 6162, 6163, 6164, 6165, 6166, 6168, 6170, 6171, 6176, 6177, 6179, 6180, 6181, 6182, 6183, 6184, 6190, 6200, 6201, 6202, 6203, 6204, 6205, 6206, 6232, 6234, 6238, 6240, 6241, 6242</li><li>2. 5620, 5621, 5622, 5623, 5627, 5630, 5633, 5646, 5647, 5648, 5803, 5806, 5807, 5809, 5811, 5812, 5831, 5832, 5835, 5839, 5861, 5862, 5863, 5864, 5868, 5870, 5871, 5872, 5873, 5874, 5875, 5959, 5960, 5962</li><li>3. 2113, 2113R, 2119, 2122, 2153</li><li>4. 2160, 2161, 2163, 2164, 2167, 2175, 2176, 2178, 2182</li><li>5. 1392, 2141, 2144L, 2146, 2147</li><li>6. 2138</li><li>7. 2114, 2114R, 2124, 2157</li><li>8. 2450, 2451, 2452, 2454, 2456</li></ol>
Basic UDI-DI	<ol style="list-style-type: none"><li>1. 06082238401010000000026AC</li><li>2. 06082238401010000000027AE</li><li>3. 06082238401010000000028AG</li><li>4. 06082238401010000000029AJ</li></ol>



	5. 06082238401010000000030A3
	6. 06082238401010000000031A5
	7. 06082238401010000000032A7
	8. 06082238401010000000033A9

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  
2510 Conway Ave. St. Paul, MN 55144 USA

7 July 2020  
Date

3M is a trademark of 3M.