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	060822384010100000000055AK

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.

- 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

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

17 August 2022

Date

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

Eko

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	1. Littmann® Cardiology IV™ Stethoscope 2. Littmann® Classic III™ Stethoscope 3. Littmann® Classic II Pediatric Stethoscope 4. Littmann® Master Cardiology™ Stethoscope 5. Littmann® Master Classic II™ Stethoscope 6. Littmann® Classic II SE Stethoscope 7. Littmann® Classic II Infant Stethoscope 8. Littmann® Lightweight II SE Stethoscope
Intended Purpose	Stethoscope
Reference	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 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 3. 2113, 2113R, 2119, 2122, 2153 4. 2160, 2161, 2163, 2164, 2167, 2175, 2176, 2178, 2182 5. 1392, 2141, 2144L, 2146, 2147 6. 2138 7. 2114, 2114R, 2124, 2157 8. 2450, 2451, 2452, 2454, 2456
Basic UDI-DI	1. 06082238401010000000026AC 2. 06082238401010000000027AE 3. 06082238401010000000028AG 4. 06082238401010000000029AJ

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	5. 0608223840101000000030A3 6. 0608223840101000000031A5 7. 0608223840101000000032A7 8. 0608223840101000000033A9

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 — 7 July 2020

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

Date