EUROPEAN MEDICAL DEVICE REGULATION

Statement

As Legal Manufacturer, we

3M Company

Single Registration Number (TBD)
2510 Conway Ave. St. Paul, MN 55144 USA

hereby declare that

the following package(s)

Name of pack(s)	3M Littmann CORE Stethoscope System
Reference	8490, 8493
Basic UDI-DI	06082238401010000000055AK

containing the following products

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

and

Product	Reference	Basic UDI-DI	Rule of Annex VIII (MDR)	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/procedure pack

and that

- all medical devices included in the above system/procedure pack are CE marked;
- the mutual compatibility of the 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/procedure pack;

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

Dianne Gibbs
Regulatory Affairs Manager
3M Company

12 January 2021
Date

Eko

DECLARATION OF CONFORMITY
MEDICAL DEVICES EKO CORE

This declaration covers the following product:

Name: Eko CORE
Model: E6

This declaration is valid for the product described here above, bearing the CE marking and manufactured at the following site(s):

1212 Broadway, Suite #100
Oakland, CA 94612
United States of America

We hereby declare under our sole responsibility that the Eko CORE (Model E6) is 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, rule 10 of Directive 93/42/EEC, 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.

Eko declares that the above mentioned product:

- meets the provision of EU Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast).
- meets the provision of EU Radio Equipment Directive 2014/53/EU (RED)

We ensure and declare that the distributed products, as mentioned and falling within Class II, 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 EUFI29-20001835-S (expiration date: 18th December 2021), EC Certificate No. C-01-1189-722-20 (expiration date: 27th May 2024) and MDSAP, certificate registration number 528011 MDSAP16 (Certificate Unique ID: 170769919; expiration date: 17th December 2021).

Notified Body:
Eurofins Expert Services Oy
Notified Body No. 0537

Eko

The following standards are used:

Standard Number	Standard Title
ISO 13485:2016	Medical Devices – Quality management systems
EN ISO 14971: 2012	Medical Devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
IEC 60601-1	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-11-2015	Medical Electrical Equipment - Part 1-11: General requirements For Basic Safety And Essential Performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-2: 2014	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility - Requirements and test
IEC 62304:2006	Medical Design Software – Software Life Cycle

Phu Trinh
VP of Regulatory & Quality Affairs
Eko Devices Inc.

2020-11-19
Date

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
Accessories	None.
Intended Purpose	Stethoscope (mechanical)
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, 6239, 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 5. 06082238401010000000030A3

	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 — 18 February 2021
Dianne Gibbs — Date
Division Regulatory Affairs Manager
3M Company
2510 Conway Ave. St. Paul, MN 55144 USA

Eko

DECLARATION OF CONFORMITY
MEDICAL DEVICES EKO ANALYSIS SOFTWARE (EAS)

This declaration covers the following product:

Name: Eko Analysis Software (EAS)

This declaration is valid for the product described here above, bearing the CE marking and manufactured at the following site(s):

Eko Devices, Inc.
1212 Broadway, Suite #100
Oakland, CA 94612
United States of America

We hereby declare under our sole responsibility that product identified above is 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, rule 10 of Directive 93/42/EEC, 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 EUFI29-20001835-S (expiration date: 18th December 2021), EC Certificate No. C-01-1189-729-20 (expiration date: 27th May 2024) and MDSAP, certificate registration number 528011 MDSAP16 (Certificate Unique ID: 170769919; expiration date: 17th December 2021).

Notified Body:
Eurofins Expert Services Oy
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Eko

The following standards are used:

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IEC 62304:2006	Medical Design Software – Software Life Cycle

Oct 8th 2020
Date

Arezou Azar, PhD.
Sr. Dir of Regulatory & Quality Affairs
Eko Devices Inc.