Masimo
52 Discovery
Irvine, CA 92618

November 22, 2024

Re: Masimo's Declaration Confirming Conditions for EU MDR Extension per Regulation 2023/607 are Fulfilled

To whom it may concern:

Masimo declares its legacy devices are covered by the transitional period stated in Regulation (EU) 2023/607, amending Regulations (EU) 2017/745. Masimo's certificate is issued by TÜV SÜD in accordance with Council Directives 93/42/EEC, was still valid on 26 May 2021, and has not been withdrawn afterwards. Masimo's EC Certificate remains valid after the expiry date of the certificate until December 31, 2028 set by EU MDR Amendment 2023/607. Masimo has fulfilled all conditions required to continue to place medical devices in the market.

Legal Manufacturer:
Masimo Corporation
52 Discovery, Irvine, CA, 92618, United States of America
SRN: US-MF-000010641

European Authorized Representative (EAR):
Medical Device Safety Services GmbH (MDSS)
Schiffgraben 41, 30175 Hannover, Germany
SRN: DE-AR-000005430

Notified Body (Council Directives 93/42/EEC)::
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany
NB ID: 0123

Certificate Number: G1 092076 0024 Rev.00 **Expiry Date:** July 15, 2023

End Date of Transitional Period: 31 December 2028

Notified Body (Regulation (EU) 2023/607, amending Regulations (EU) 2017/745):
Intertek Medical Notified Body AB
Torshamnsgatan 43, Box 1103
SE-164 22 Kista
NB ID: 2862

Device Classification: IIa, IIb

Devices Covered by Extension: Pulse Oximeters and Accessories (Cables and Sensors), Telemetric Physiologic Monitoring System, Respiratory Monitors and Accessories (Cables and Sensors), EEG Monitors and Accessories (Cables and Sensors), Regional Oximeters and Accessories (Cables and Sensors), Physiologic Monitoring Systems (for Blood Pressure and Body Temperature), Capnography Monitors and Accessories (Sampling Lines and Cannulas), ECG Monitors and Accessories (ECG Electrodes), Patient Position Monitoring System.

Conditions laid down in Article 120(3c) as amended by regulation 2023/607.

a. Masimo medical devices continue to comply with Council Directive 93/42/EEC;
b. There are no significant changes in the design and intended purpose of Masimo's medical devices;
c. Masimo medical devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
d. Masimo Corporation has put in place a quality management system in accordance with Article 10(9).
e. Masimo has lodged a formal application with TÜV SÜD covering all Masimo medical devices. Masimo and TÜV SÜD have signed a written agreement in accordance with Regulation 2023/607.

Sincerely,

Karla Guerrero
Associate Director, Audits & Compliance
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