LUMED®
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Magazzino e Produzione
Production Site & Logistics
Via Senio 36/40
47121 Forlì (FC) - Italy
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DECLARATION OF CONFORMITY

The Manufacturer

Lumed Srl

Via Serio 10

20073, Opera (MI)

Italy

Declare under his own responsibility that the device

ECG Patient Cables

Intended use

ECG patient cables are intended to be used in conjunction with cardiac function study equipment and in particular for electrocardiogram acquisition.

Basic UDI-DI: 805750665 FT04 DS
SRN: IT-MF-000009110

Ref.	Risk Class (MDR 2017/745 – Annex VIII)
EE100XXX-200 EE100XXXX-200, EE100XXXX-350, EE103XX-XXX EE200XXXX-XXX, EE203XX-XXX, EE300XXXX-XXX	I

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It complies with the General Safety and Performance Requirements set forth in Annex I of EU Regulation 2017/745 on Medical Devices, and that the conformity assessment process referred to Annex II and Annex III of EU Regulation 2017/745 on Medical Devices was followed

ROHS

It complies with the provisions of Directive 2011/65/EU and s.a., relating to the restriction of the use of certain hazardous substances in electrical and electronic equipment, implemented in Italy by Legislative Decree No. 27 and s.a., released on March 4, 2014.

Opera, 21/01/2025 ……..

Place, Date

FABIO MAFFEZZOLI

Quality & Regulatory Affairs Specialist, PRRC