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DECLARATION OF CONFORMITY

The Manufacturer

Lumed Srl

Via Staffora 18/9
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Declare under his own responsibility that the device

Recording Papers for Medical Devices

Intended Use

Thermal papers are used for recording biological signals from electromedical instruments

Basic UDI-DI:805750665 FT03 DQ

SRN: IT-MF-000009110

Ref.	Risk Class (MDR 2017/745 – Annex VIII)
BS47nn nn nn/Dnn, BS47nn nn nn/l, BS47nn nn nn/S, CFNKnnn, CFSNnnn	I

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 in Annex II and Annex III of EU Regulation 2017/745 on Medical Devices was followed.

Opera, 13/10/2022

Place , Date

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FABIO MAFFEZZOLI

Quality & Regulatory Affairs Specialist, PRRC

LUMED is the Italian distributor of:



SEDE LEGALE: Via Vittor Pisani 28 – 20124 Milano
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CCIAA / NREA: MI – 1631065
Capitale Sociale: € 77.000,00 interamente versato
Registro Imprese di Milano: 03050700966