

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1497993-1

Manufacturer: M4Medical Sp. z o.o.
ul. Nałęczowska 14
20-701 Lublin
Poland

Products: – Electrocardiographs
– Standalone software for analysis and presentation of ECG signals

Replaces EC Certificate number HD 60139433 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 84953582-40

Effective date: 2021-05-23

Expiry date: 2024-04-23

Issue date: 2021-05-23

Suierafacis

Maciej Sciera
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	M4Medical Sp. z o.o. ul. Nałęczowska 14 20-701 Lublin Poland	Activity: Administration
/02	M4Medical Sp. z o.o. ul. Zielona 1C 32-082 Bolechowice Poland	Activity: Design and development, manufacture of electrocardiographs and standalone software for analysis and presentation of ECG signals

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Sciera Francis


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