

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1497993-1

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

Scope: Design and development, production, distribution
and servicing of electrocardiographs and standalone software
for analysis and presentation of ECG.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84980832-20

Effective date: 2025-04-24

Expiry date: 2028-04-23

Issue date: 2025-04-22

Replaces certificate SX 1497993-1 issued 2023-12-19

This certificate can be validated on <https://www.certifedia.com>



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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	M4Medical Sp. z o.o. ul. Nałęczowska 14 20-701 Lublin Poland	Administration.
/02	M4Medical Sp. z o.o. ul. Zielona 28 32-082 Bolechowice Poland	Design and development, production, distribution and servicing of electrocardiographs and standalone software for analysis and presentation of ECG.

This certificate can be validated on <https://www.certivoxa.com>