Certificate HU19/8476

The quality management system of

Meditech Kft.

Mikszáth Kálmán u. 24., Budapest 1184, Hungary
Facility number: F003261

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System
Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009 - Vigilance
Canada: Medical Device Regulations SOR/98-282, Part 1
USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities
Design, development manufacture and service of electronic blood pressure meters and ECG instruments and related software

This certificate is valid from Effective date 2024-06-27 until Expiry date 2027-06-27 and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 2019-12-17

L. Henderson

Authorised by
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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.