Certificate HU19/8476

The management system of

Meditech Kft.

1184 Budapest, Mikszáth Kálmán u. 24., Hungary

Facility Identification Number: F003261

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System
Brazil Jurisdictions:
RDC ANVISA n. 16/2013 - Good Manufacturing Practices
RDC ANVISA n. 23/2012
RDC ANVISA n. 67/2009 - Vigilance
Canada:
Medical Devices Regulations – Part 1 SOR 98/282
United States:
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 and manufacture of electronic blood pressure meters and ECG instruments

This certificate is valid from Effective Date: 03 June 2022 until Expiry Date: 27 June 2024 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 May 2024

Issue 2. Certified since 17 December 2019

Authorised by

L. Henderson

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