145139-21-05-25

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Kft. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

MEDITECH Egészségügyi Szolgáltató, Műszerfejlesztő és Kereskedelmi KFT.

Headquarters: **1184 Budapest, Mikszáth Kálmán utca 24., Hungary**

Scope:

Combined ambulatory blood pressure monitor

The certificate covers the following devices:

Description of the device	Type (Reference)	Intended use	Model Brand name	Risk class
Combined Ambulatory blood pressure monitor	CT2	Ambulatory blood pressure measurement, ECG Holter and Actigraphy	card(X)plore Meditech card(X)plore	II.a

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 183-CE-190226

Issue: 1
Issued: 25 May 2021
First issued: 25 May 2021
Start date of certified status: 22 June 2019

Expires:
25 May 2024

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Valter PAPP, Dr.
General Manager

CE Certiso Ltd. NB2409 Notified Body

CE Certiso Kft.
H-2092 Budakeszi, Erdő utca 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409