# 145137-21-05-25

# 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:

**ECG Holter monitor**

The certificate covers the following devices:

| Description of the device | Type (Reference) | Intended use | Model Brand name | Risk class |
|---|---|---|---|---|
| ECG Holter monitor | FC1 | EKG Holter | CardioMera<br>Meditech CardioMera | 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

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