

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 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

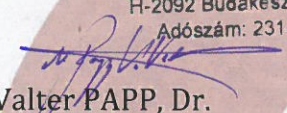
Issue: 1

Issued: 25 May 2021

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Start date of certified status: 22 June 2019

Expires:

25 May 2024**CE Certiso**Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
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