

EC Certificate Full Quality Assurance System: Certificate HU15/7716

The management system of

Meditech Kft.

H - 1184 Budapest, Mikszáth Kálmán u. 24.

has been assessed and certified as meeting the requirements of

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

For the following products

ABPM, BlueBP electronic blood pressure meters; CardioMera, CardioBlue, CardiUPI, ECG recorders and card(X)plore ambulatory blood pressure and holter ECG monitor; apneABP combined ambulatory blood pressure pulse oximeter and activity monitor, CardioVisions and EasyABPM software for cardiovascular data management, analysis and reporting

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 8 May 2018 until 27 June 2023 and remains valid subject to manufacturer surveillance audits. Re certification audit due before 13 May 2021 Issue 17. Certified since 30 June 1997

Certification is based on reports numbered HU/BUD-HU0163MD

Authorised by

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Canceled upon Meditech's request. 01st June, 2019.
Last effective day:

