

EC Certificate Full Quality Assurance System: Certificate HU15/7716

The management system of

Meditech Kft.

1184 Budapest, Mikszáth Kálmán u. 24. Hungary
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 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 28 June 2015 until 27 June 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 May 2018
Issue 15. Certified since 30 June 1997

Certification is based on reports numbered HU/BUD HU0163QYH

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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