OFFICE OF HEALTH
AUTHORISATION AND ADMINISTRATIVE PROCEDURES
DEPARTMENT OF MEDICAL DEVICES

Address: H-1051 Budapest, Zrínyi utca 3.
Telefon: (+36-1) 302-5060, (+36-1) 235-7914
Facsimile: (+36-1) 269-1255
PO Box: H-1380 Budapest, Pf.: 1188
Internet: http://www.eekh.hu
E-mail: amd@eekh.hu

Subject: Certificate for third countries
Reference: 1849-004/2014/OTIG

Supplement: -

Admin.ref.: Eszter Ádám

FREE SALES CERTIFICATE

On request of the **Meditech Kft.** (H-1184 Budapest, Mikszáth Kálmán u. 24., Hungary) the Department of Medical Devices of the Office of Health Authorisation and Administrative Procedures certifies on the basis of the demonstrated documents that the following medical device(s) manufactured by the above firm, fulfil(s) the legal requirements of placing the device(s) on the Hungarian market:

1. BlueBP-05: Bluetooth-capable ambulatory blood pressure monitor
2. ABPM-05: miniature ambulatory blood pressure monitor
3. ABPM-04: ambulatory blood pressure monitor
4. card(X)plore: Holter ECG and BP monitor with activity logging
5. apneABP: Ambulatory blood pressure monitor and pulse oximeter
6. CardioTens: 24-hour blood pressure and ECG monitor
7. CardioMera: full disclosure digital Holter ECG
8. CardioBlue24: full disclosure Holter ECG with Bluetooth communication
9. CardioBlue: ECG event recorder with wireless Bluetooth communication
10. CardioClip: looping ECG event recorder
11. merlin: ECG event recorder, single-channel ECG built in a wristwatch
12. E-Lite: 12-lead resting ECG

This certificate has been issued for alien use to support the application for permission of placing the above mentioned devices on the market.

The regulations of sales in Hungary contain regulations compatible with the Council Directive 93/42/EEC concerning medical devices as well as the Council Directive 90/385/EEC on active implantable medical devices.

Budapest, 17 January 2014

on behalf of President dr. Rita Paphalmi
acting within the task and competence of the Office:

Péter Bunyitai
Head of Department