

Case No.: **OGYÉI/7772-3/2018**

Subject: Certificate for third countries

Consultant: Anikó Gyórfi

## FREE SALES CERTIFICATE

On request of the **Meditech Kft.** (1184 Budapest, Mikszáth Kálmán u. 24. Hungary) the National Institute of Pharmacy and Nutrition hereby certifies, that on the basis of information provided, the medical device(s) named below and detailed in the attachment (if applicable), which is/are manufactured by the above economic operator, has/have been affixed with the CE mark under the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices and/or the Council Directive 93/42/EEC concerning medical devices (as amended) which was transposed into Hungarian national law [decree No. 8/2003. (III. 13) of the Minister of Health, Social and Family Affairs on in vitro diagnostic medical devices and /or decree No. 4/2009 (III. 17) of the Minister of Health on medical devices, as amended] may be freely sold in all member states of the European Economic Area (EEA) including Hungary.

Number	Product name	Description
1	ABPM	Electronic blood pressure meters (ambulatory blood pressure monitor)
2	BlueBP	Electronic blood pressure meters (ambulatory blood pressure monitor with Bluetooth)
3	CardioMera	ECG recorders (full disclosure digital Holter ECG)
4	CardioBlue	ECG recorders (ECG event recorder with Bluetooth)
5	CardiUP!	ECG recorders (full disclosure digital Holter ECG)
6	card(X)plore	card(X)plore ambulatory blood pressure and holter ECG monitor
7	apneABP	Combined ambulatory blood pressure, pulse oximeter and activity monitor
8	CardioVisions	Software for cardiovascular data management, analysis and reporting
9	EasyABPM	Software for cardiovascular data management, analysis and reporting

This certificate has been issued to Hungarian exporters for use in non-EU (EEA EFTA) third countries to support the application for permission of placing the above mentioned devices on the market. A Free Sales Certificate should not be taken as a Government endorsement of any product that is referred to on the certificate or its attachment.

Budapest, 13 April 2018

On behalf of Dr. Csilla Pozsgay  
Director General

