

Case No.: **OGYÉI/41343-3/2021**
Subject: Certificate for third countries
Consultant: Gábor Szlobodnyik

FREE SALES CERTIFICATE

On request of the **MEDITECH Egészségügyi Szolgáltató, Műszerfejlesztő és Kereskedelmi KFT.** (1184 Budapest, Mikszáth Kálmán utca 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 Ministry of Health, Social and Family Affairs on in vitro diagnostic medical devices and /or decree No. 4/2009 (III. 17) of the Ministry of Health on medical devices, as amended] may be freely sold in all member states of the European Economic Area (EEA) including Hungary.

Number	Description of the device	Type	Intended use	Model Brand name
1	Ambulatory blood pressure monitor	BP4	Ambulatory blood pressure measurement	ABPM-04 Meditech ABPM-04
2	Ambulatory blood pressure monitor	BP5	Ambulatory blood pressure measurement	ABPM-05 Meditech ABPM-05 Omrom M24/7 Omron M24/7P BIOS Diagnostics ABP-01
3	Ambulatory blood pressure monitor	BP6	Ambulatory blood pressure measurement	ABPM-06 Meditech ABPM-06
4	ECG Holter monitor	FC1	ECG Holter	CardioMera Meditech CardioMera
5	ECG Holter monitor	ED1	ECG Holter	CardiUP!3 Meditech CardiUP!3 CardiUP!12

				Meditech CardiUP!12
6	Combined ambulatory blood pressure monitor	CT2	Ambulatory blood pressure measurement, ECG Holter and Actigraphy	card(X)plore Meditech card(X)plore
7	Cardiovascular data management software	SWN	Data management, analysis, reporting	CardioVisions Meditech CardioVisions Omron BP Tracker Software
8	Cardiovascular data management software	SA1	Data management, analysis, reporting	EasyABPM Meditech EasyABPM

This certificate has been issued to Hungarian exporters for use in 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, 05 July 2021



 dr. Kornél Szerdi
 Head of Department