



Case No.: **OGYÉI/16655-3/2020**  
Subject: Certificate for third countries  
Consultant: Henrietta Kopornoky

## FREE SALES CERTIFICATE

On request of the **Labtech Kft.** (4031 Debrecen, Vág u. 4. 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.

### EC type Holter systems

with **Cardiospy** software

including **EC-2H, EC-3H, EC-12H, EC-ABP, EC-3H/ABP** models

### EC type resting and stress test ECG systems

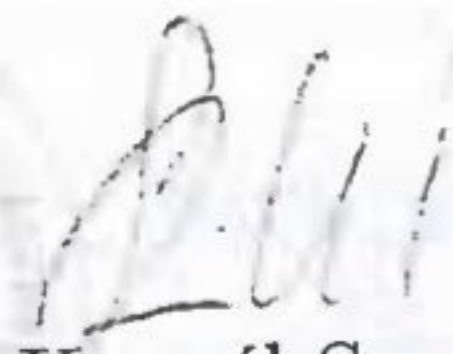
with **Cardiospy** software

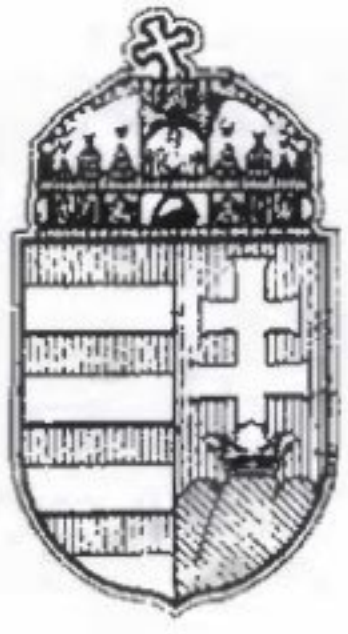
including **EC-12R, EC-12RM, EC-12S, EC-12R/S, EC-3RT, EC-12RT, EC-12LT** models

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, 19 March 2020

  
dr. Kornél Szerdi  
Head of Department



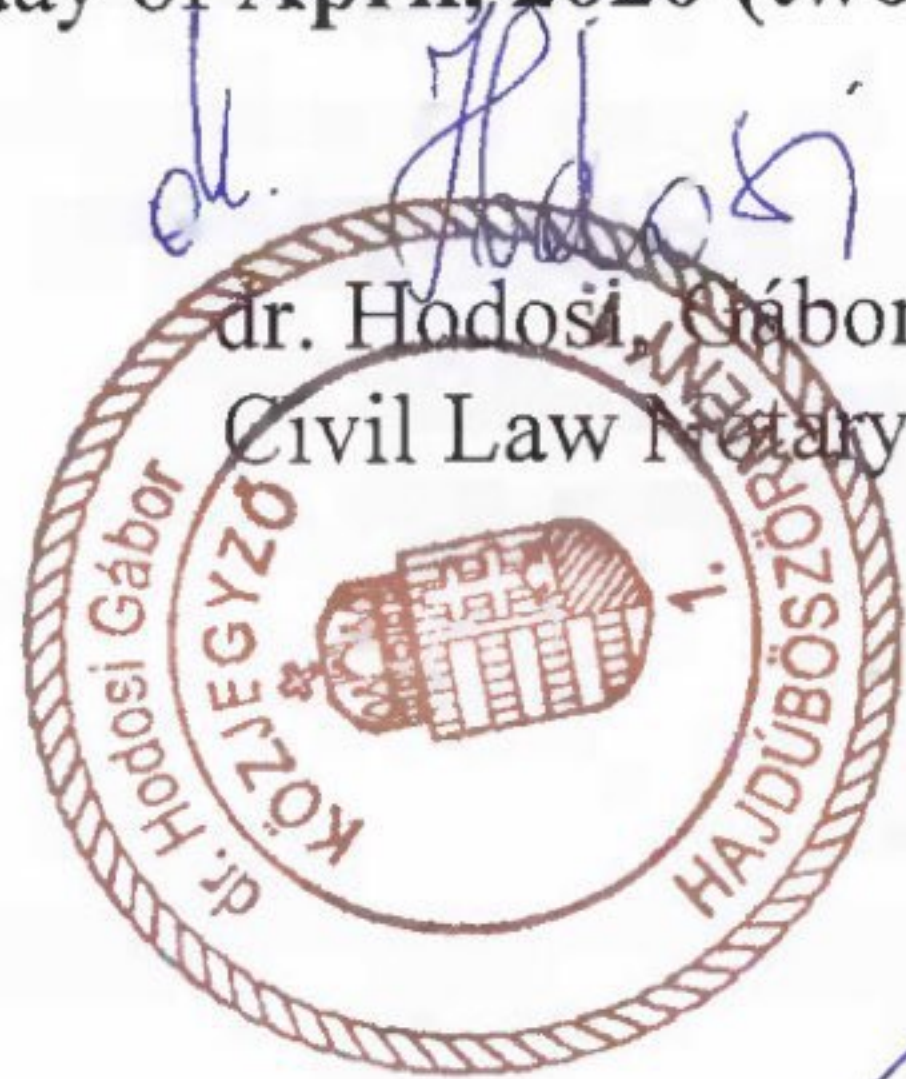
dr. Hodosi, Gábor  
Civil Law Notary

holder of a language license in English and German  
appointed to Notarial Seat No. 1 of Hajdúböszörmény  
official electronic contact information in short: MOKKIT  
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H-4220 Hajdúböszörmény, Hungary, Bocskai tér 2.  
Tel: + 36 52 561-042 , Tel: + 36 52 561-043  
Email: iroda.hodosi@kozjegyzo.hu

English language license No: 2/2017.  
File No: 32018/Z/297/2020.

I the undersigned Notary in and for the City of Hajdúböszörmény hereby certify that this document on the other side is a true and faithful copy of the document, name of "FREE SALES CERTIFICATE", which bears one signature (which is seemed to be original), one stamp (which is seemed to be original) having been produced to me as original.-----  
At Hajdúböszörmény on the 8th (eighth) day of April, 2020 (two thousand and twenty). -

The Ministry of Foreign Affairs and Trade of Hungary certifies the seal and signature of the Hungarian Chamber of Civil Law Notaries appearing on this document.



Legalisation fee paid: 5.500,- HUF  
Date: 2020.08.04  
Registration nr.: 003081/1

A01/2020/5809  
A fenti aláírás és bélyegzőlenyomat  
tételül.

dr. Engler Dóra  
Head of the Legalisation Unit



Budapest, 2020 AUG 06.

aláírás  
dr. Brezovszki Andrea  
jogi előadó



Đại sứ quán nước CHXHCN  
Việt Nam tại CH Hungary  
HỢP PHÁP HÓA LÃNH SỰ  
Số: 133/LS-HPH

Chúng thực chữ ký của ông/bà

.....  
Dr. Engler Dóra  
và con dấu của (cơ quan)  
.....  
Bộ Ngoại giao Hungary  
.....  
Budapest ngày: 13.10.2020



ĐẠI SỨ QUÁN VIỆT NAM TẠI HUNGARY  
ĐẠI SỨ  
Bí thư thứ ba  
NGUYỄN THÁI HÀ