

Case No.: **OGYÉI/29992-3/2021**
 Subject: Certificate for third countries
 Consultant: Henrietta Kopornoky

FREE SALES CERTIFICATE

On request of the **DIATRON MI Zrt. (1097 Budapest, Táblás u. 39. 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.

Product code	Product name
APK300	Autopak 300 Clinical Chemistry Autoanalyzer
APK300i	Autopak 300 Clinical Chemistry Autoanalyzer with ISE Module

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, 13 May 2021

The Ministry of Foreign Affairs and Trade of Hungary certifies the seal and signature of **ORSZÁGOS GYÓGYSZERÉSZETI ÉS ÉLELMÉZÉS-EGÉRSÉGÜGYI INTÉZET Zrt.**

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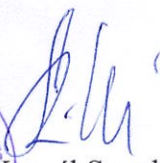
Legalisation fee paid: **55.00** HUF

Date: **2021 AUG 10.**

Registration nr.: **CAAO3703/04**


 dr. Németh Annamária
 Desk Officer




 dr. Kornél Szerdi
 Head of Department

Đại sứ quán nước CHXHCN
Việt Nam tại CH Hungary

HỢP PHÁP HÓA LÃNH SỰ
Số 336./LS-HPH

Chứng thực chữ ký của ông/bà
.....*Németi Anna Andriá*.....

và con dấu của (cơ quan)
.....*Bộ Ngoại giao Hungary*.....

Budapest ngày *18.10.2021*

ĐSQVN TẠI HUNGARY
TL. ĐẠI SỨ

bi' thư thứ nhất



Nguyễn Hồng Bàng



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Dr. Nórah Ánna Andriá
Desk Officer