

Case No.: **OGYÉI/4160-3/2021**
Subject: Certificate for third countries
Consultant: Gábor Szlobodnyik

FREE SALES CERTIFICATE

On request of the **Reagens Kft.** (1155 Budapest, Wysocki u. 1., 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.

Cikkszám	Termék megnevezés	Konc.	Kiszerezés
11114	ReaSol hígító		
13100-10	Bromelin		
13110-04	AGGI-LISS		
13110-10	AGGI-LISS		
15015-10	Pufferolt fiziológias sóoldat		
15020-03	Pufferolt fiziológias sóoldat Plus		
21217-10	Aktív Papain		
31010	REAG-QUICK Panoptic		
31011	REAG-FIX Panoptic		
31012	REAG-QUICK Panoptic		
31015	REAG-BLUE Panoptic		
31016	REAG-RED Panoptic		
31017	REAG-FIX Panoptic		
31018	REAG-RED Panoptic		
31019	REAG-BLUE Panoptic		
32011	RETI-COLOR		
41100	ReaCell I, II, III	3±0,5%	3x5 ml
41120	ReaCell I, II, III	3±0,5%	3x10 ml
41150	ReaCell I, II, III	0,8±0,1%	3x5 ml
41180	ReaCell I, II, III	0,8±0,1%	3x10 ml
41200	ReaCell IP, IIP, IIIP	3±0,5%	3x5 ml
41220	ReaCell IP, IIP, IIIP	3±0,5%	3x10 ml
41250	ReaCell IP, IIP, IIIP	0,8±0,1%	3x5 ml
41270	ReaCell IP, IIP, IIIP	0,8±0,1%	3x10 ml



42140	ReaCell AB0 A1 A2 B 0	5-10%	4x10 ml
42150	ReaCell AB0 A1 A2 B 0	3±1%	4x10 ml
42170	ReaCell AB0 A1 A2 B 0	1,5±0,5%	4x10 ml
42180	ReaCell AB0 A1 B	3±1%	2x10 ml
42190	ReaCell AB0 A1 A2 B	3±1%	3x10 ml
42200	ReaCell AB0 A1 B 0	3±1%	3x10 ml
42210	ReaCell AB0 A1 A2 B 0	3±1%	4x5 ml
42220	ReaCell AB0 A1 B	3±1%	2x5 ml
42230	ReaCell AB0 A1 A2 B	3±1%	3x5 ml
42240	ReaCell AB0 A1 B 0	3±1%	3x5 ml
42250	ReaCell AB0 A1 B	5-10%	2x10 ml
42260	ReaCell AB0 A1 A2 B	5-10%	3x10 ml
42270	ReaCell AB0 A1 B 0	5-10%	3x10 ml
42280	ReaCell AB0 A1 A2 B 0	5-10%	4x5 ml
42290	ReaCell AB0 A1 B	5-10%	2x5 ml
42300	ReaCell AB0 A1 A2 B	5-10%	3x5 ml
42310	ReaCell AB0 A1 B 0	5-10%	3x5 ml
42400	ReaCell AB0 A1 A2 B 0	1,5±0,5%	4x20 ml
42500	ReaCell AB0 A1 A2 B 0	0,8±0,1%	4x5 ml
42520	ReaCell AB0 A1 A2 B 0	0,8±0,1%	4x10 ml
42530	ReaCell AB0 A1 A2 B 0	0,8±0,1%	2x10 ml
42540	ReaCell AB0 A1 A2 B 0	0,8±0,1%	3x10 ml
42550	ReaCell AB0 A1 A2 B 0	0,8±0,1%	3x10 ml
42560	ReaCell AB0 A1 B	0,8±0,1%	2x5 ml
42570	ReaCell AB0 A1 A2 B	0,8±0,1%	3x5 ml
42580	ReaCell AB0 A1 B 0	0,8±0,1%	3x5 ml
43100	ReaCell Panel	3±0,5%	11x5 ml
43200	ReaCell Panel P	3±0,5%	11x5 ml
43500	ReaCell Panel	0,8±0,1%	11x5 ml
43800	ReaCell Panel P	0,8±0,1%	11x5 ml
44130	Rea IQC Total Blood Kit	15%	4x6 ml
44140	Rea IQC Total Blood Kit	15%	4x4 ml
44200	Rea QC	15%	2x5 ml
ATM-1K	Virus Transport Medium Kit		
AVE-100	AviRNA Viral RNA Extraction Kit		
CQ-100	Cov2Quant SARS-Cov-2 Quantification Kit		
ICQ-100	Inf-Cov2Quant - Influenza A/B + SARS-CoV-2 Quantification Kit		

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, 29 January 2021


 dr. Kornél Szerdi
 Head of Department
 