OFFICE OF HEALTH AUTHORISATION AND ADMINISTRATIVE PROCEDURES

DEPARTMENT OF MEDICAL DEVICES

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Subject: Certificate
Case number: 60076-002/2014/OTIG
Registration No.: HU/CA01/60076/14
Consultant: Ádám Eszter
Supplement: -

The Department of Medical Devices of the Office of Health Authorisation and Administrative Procedures according to the Article 7, point (3) of the Decree No. 8/2003.(III.13.) EszCsM on „In vitro diagnostic medical devices" (in the following IVD-decree) harmonizing the 98/79/EC Directive on In vitro diagnostic medical devices

c e r t i f i e s

that the Diagon Ltd. (1047 Budapest, Baross u. 48-52.) has notified the following IVD-devices according to points (1) of Article 7 of the IVD-decree.

Device category (due to ISO 15225:2000): In vitro diagnostic medical devices
Name of the device(s):

	Code	Name	Unit, ml
1.	DC7VL	D-Check 7 Low	2,0
2.	DC7VN	D-Check 7 Normal	2,0
3.	DC7VH	D-Check 7 High	2,0
4.	DC8VL	D-Check 8 Low	2,0
5.	DC8VN	D-Check 8 Normal	2,0
6.	DC8VH	D-Check 8 High	2.0
7.	DC18VL	D-Check 18 Low	2,0
8.	DC18VN	D-Check 18 Normal	2.0
9.	DC18VH	D-Check 18 High	2.0
10.	DC18T5L	D-Check 18 Low	5,0
11.	DC18T2L	D-Check 18 Low	2,0
12.	DC18T2N	D-Check 18 Normal	2,0
13.	DC18T2H	D-Check 18 High	2,0
14.	DC18T5N	D-Check 18 Normal	5,0
15.	DC18T5H	D-Check 18 High	5,0
16.	DC3TL	D-Check 3P Low	3,0
17.	DC3TN	D-Check 3P Normal	3,0
18.	DC3TH	D-Check 3P High	3,0
19.	DCCD3RT1	D-Check CD3Ret	3,0
20.	DCCD3RT2	D-Check CD3Ret	3,0
21.	DCCD4KTL	D-Check CD4K Low	3,0
22.	DCCD4KTN	D-Check CD4K Normal	3.0
23.	DCCD4KTH	D-Check CD4K High	3,0
24.	DCCD4RT1	D-Check CD4Ret	3,0
25.	DCCD4RT2	D-Check CD4Ret	3,0
26.	DCA120T1	D-Check A120 Ret	4,0

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27.	DCA120T2	D-Check A120 Ret	4,0
28.	DCA120T3	D-Check A120 Ret	4,0
29.	DC18PT2L	D-Check 18 Plus Low	2,5
30.	DC18PT2N	D-Check 18 Plus Normal	2,5
31.	DC18PT2H	D-Check 18 Plus High	2,5
32.	DC18PTL	D-Check 18 Plus Low	4,0
33.	DC18PTN	D-Check 18 Plus Normal	4,0
34.	DC18PTH	D-Check 18 Plus High	4,0
35.	DCSTL	D-check SYS Low	4,5
36.	DCSTN	D-check SYS Normal	4,5
37.	DCSTH	D-check SYS High	4,5
38.	DCTTL	D-Chech Tech Low	3,5
39.	DCTTN	D-Chech Tech Normal	3,5
40.	DCTTH	D-Chech Tech High	3,5
41.	DCXETL	D-Check XE Low	4,5
42.	DCXETN	D-Check XE Normal	4,5
43.	DCXETH	D-Check XE High	4,5
44.	DC4KRTL	D-Check CD4KRet Low	3,0
45.	DC4KRTN	D-Check CD4KRet Normal	3,0
46.	DC4KRTH	D-Check CD4KRet High	3,0
47.	DC5DTL	D-Check C5D Low	5,0
48.	DC5DTN	D-Check C5D Normal	5,0
49.	DC5DTH	D-Check C5D High	5,0
50.	DCRETIV1	D-Check Ret-I 1V	1,5
51.	DCRETIV2	D-Check Ret-I 2V	1,5
52.	DCRETIV3	D-Check Ret-I 3V	1,5
53.	DCRETIT1	D-Check Ret-I 1T	3,0
54.	DCRETIT2	D-Check Ret-I 2T	3,0
55.	DCRETIT3	D-Check Ret-I 3T	3,0
56.	DCRETP1	D-Check Ret P 1	4,0
57.	DCRETP2	D-Check Ret P 2	4,0
58.	DCRETP3	D-Check Ret P 3	4,0
59.	DST1	D-Sed-Plus level 1	4,5
60.	DST2	D-Sed-Plus level 2	4,5
61.	DSV1	D-Sed-Plus level 1	9,0
62.	DSV2	D-Sed-Plus level 2	9,0
63.	DCALCD	D-Cal CD	3,0
64.	DCALNEK	D-Cal NEK	3,5
65.	DCALP	D-Cal Plus	4,5
66.	DCALTECH	D-Cal TECH	3,5
67.	DCXERET1	D-Check XE-RET Level 1	3,0
68.	DCXERET2	D-Check XE-RET Level 2	3,0
69.	DCXERET3	D-Check XE-RET Level 3	3,0
70.	DCXENRBC1	D-Check XE-nRBC Level 1	4,5
71.	DCXENRBC2	D-Check XE-nRBC Level 2	4,5
72.	DCXENRBC3	D-Check XE-nRBC Level 3	4,5

Name of manufacturer: Diagon Ltd.
Code of manufacturer: HU/10831050-2-41

This certificate has been issued to the manufacturer in the procedure launched on the request presented on 19 November 2014, on the basis of documents available, in order to certify that notification according to Article 7 of the IVD-decree has been done.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of „in vitro medical device", and that you have classified it/them as falling within the IVD-decree. In accepting your registration, I should make clear that the Department of Medical Devices does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the Hungarian Competent Authority.

This Certificate has been issued instead of the Certificate Ref. Number HU/CA01/64927/10 because of modification of the product list. From this time the Certificate Ref. Number HU/CA01/64927/10 is no longer valid.

Budapest, 27 November 2014

on behalf of President dr. Rita Paphalmi acting
within the task and competence of the Office:

Egészségügyi Engedélyezési és Közigazgatási Hivatal
Orvostechnikai Főosztály

Péter Bunyitai
Head of Department

Receivers are as follows:
Diagon Ltd. (1047 Budapest, Baross u. 48-52.)
Archives

REPUBLICA MOLDOVA mun. CHISINAU
PENTRU FACTURI
S.R.L.
PROFILABDIAGNOSTIC
IDNO 1006600