DIAGON
Solutions beyond imagination

CE

Manufacturer 's Declaration of Conformity

Manufacturer's name: **Diagon Ltd.**

Manufacturer's registered place of business:
1047 Baross str. 48-52, Budapest, Hungary

declares in our own responsibility conformity of the products listed in the **Appendix I.** below, according to the essential requirements Annex I of the Directive 98 / 79 / EC on *in vitro* diagnostic medical devices (IVD Directive):

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (class: other IVD products) of the Directive 98 / 79 / EC, except of Point 6.

IVD Category: Non-listed according to IVDD (Others)

I declare that the use of the device(s) under appropriate conditions as described in product instructions of use will not compromise the health or safety of the patient, the user or other involved person.
I will ensure to institute and to keep up to date a quality system which enables me to review experiences gained from the device(s) in the post-production phase and to implement the necessary corrective actions.

Digitally signed by Stoianova Elena
Date: 2025.07.15 12:46:25 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Diagon Ltd.
Budapest, 13.03.2023

Signature: .....
Name of Authorized Signatory: Levente Szén
Position held in company: Head of QA

DIAGON LTD
1047 Budapest, Baross u. 48-52
HUNGARY

SGS SGS SGS Diagon Ltd. - Hungary 1047 Budapest, Baross u. 48-52. 1325 Újpest Pf.41 tel: (+36 1) 369 6500 fax: (+36 1) 369 6501 e-mail: diagon@diagon.com www.diagon.com

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Appendix I.

Ref. No.	Product name	CE Registration No.
h30101	Diaton Erma Diluent	HU/CA01/61676/15
h30102	Diadriplyse-Erma	HU/CA01/61676/15
h30103	Dialyse Erma	HU/CA01/61676/15
h30109	Dialyse ERMA CF	HU/CA01/61676/15

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Manufacturer's registered place of business:
1047 Baross str. 48-52, Budapest, Hungary

declares in our own responsibility conformity of the products listed in the **Appendix I.** below, according to the essential requirements Annex I of the Directive 98 / 79 / EC on *in vitro* diagnostic medical devices (IVD Directive):

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (class: other IVD products) of the Directive 98 / 79 / EC, except of Point 6.

IVD Category: Non-listed according to IVDD (Others)

I declare that the use of the device(s) under appropriate conditions as described in product instructions of use will not compromise the health or safety of the patient, the user or other involved person.
I will ensure to institute and to keep up to date a quality system which enables me to review experiences gained from the device(s) in the post-production phase and to implement the necessary corrective actions.

Diagon Ltd.
Budapest, 22.12.2021.

Signature: ....
Name of Authorized Signatory: Rozália Flórika-Katona
Position held in company: Deputy Managing Director

SGS SGS SGS Diagon Ltd. - Hungary 1047 Budapest, Baross u. 48-52. 1325 Újpest, Pf.41 tel.: (+36 1) 369 6500 fax: (+36 1) 369 6301 e-mail: diagon@diagon.com www.diagon.com

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Appendix I.

Diagon Ltd Ref. No.	Diagon Ltd Product name	CE Registration No.
h23101, h23111	Diaton-SYS Diluent	HU/CA01/29777/2019
h23102, h23112, h23122, h23132	Diadriplyse-SYS	HU/CA01/29777/2019
h23103, h23113	Diaresh-SYS	HU/CA01/29777/2019
h23104, h23114, h23124	Diamox-SYS-WM2	HU/CA01/29777/2019
h23105, h23115, h23125	Dialyser-SYS-SHB	HU/CA01/29777/2019
h23106, h23116, h23126, h23136	Diaclean-SYS	HU/CA01/29777/2019
h23202, h23212	Diasheath-SYS	HU/CA01/29777/2019
h23203, h23213	Diastromlyser-SYS-C	HU/CA01/29777/2019
h23204, h23214	Diastromlyser-SYS-WP	HU/CA01/29777/2019
h23205, h23215, h23225	Diastromlyser-SYS-3WP	HU/CA01/29777/2019
h23207, h23217, h23227	Diamox-SYS-W	HU/CA01/29777/2019
h23301, h23311	Diastromlyser-SYS-FD-I	HU/CA01/29777/2019
h23302, h23312	Diastromlyser-SYS-FD-II	HU/CA01/29777/2019
h23303, h23313	Diastromlyser-SYS-FBA	HU/CA01/29777/2019
h23401, h23411	Diastromlyser-SYS-WH	HU/CA01/29777/2019
h23601	Diastromlyser-SYS-4DL	HU/CA01/29777/2019
h23602, h23622	Diastromlyser-SYS-4DS-Dye	HU/CA01/29777/2019
h23603	Diastromlyser-SYS-NR	HU/CA01/29777/2019
h23604	Diastromlyser-SYS-NR-Dye	HU/CA01/29777/2019
h23605, h23615	Diastromlyser-SYS-IM	HU/CA01/29777/2019
h23606	Diaretic-II-SYS-Buffer	HU/CA01/29777/2019
h23607	Diaretic-II-SYS-Dye	HU/CA01/29777/2019
h23613	Diastromlyser-SYS-NR-Kit	HU/CA01/29777/2019
h23616	Diaretic-II-SYS-Kit	HU/CA01/29777/2019
h23801, h23811	Diacatch-SYS-Diluens	HU/CA01/29777/2019
h23802, h23812	Diasheath-U	HU/CA01/29777/2019
h23803, h23813, h23823	Diacatch-SYS-Dye	HU/CA01/29777/2019
h51101, h51111, h51121	Diaclean-Cell	HU/CA01/29777/2019
h34101	DiaSheath U II	HU/CA01/29777/2019

FIRMA STIINTIFICA DE PRODUCTIE «DAC-SPECTROMED» S.R.L. IDNO 1002600042432 -2- REPUBLICA MOLDOVA, mun. CHISINAU

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DIAGON
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CE

Manufacturer 's Declaration of Conformity

Manufacturer's name: **Diagon Ltd.**

Manufacturer's registered place of business:
1047 Baross str. 48-52, Budapest, Hungary

declares in our own responsibility conformity of the products listed in the **Appendix I.** below, according to the essential requirements Annex I of the Directive 98 / 79 / EC on *in vitro* diagnostic medical devices (IVD Directive):

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (class: other IVD products) of the Directive 98 / 79 / EC, except of Point 6.

IVD Category: Non-listed according to IVDD (Others)

I declare that the use of the device(s) under appropriate conditions as described in product instructions of use will not compromise the health or safety of the patient, the user or other involved person.
I will ensure to institute and to keep up to date a quality system which enables me to review experiences gained from the device(s) in the post-production phase and to implement the necessary corrective actions.

DIAGON LTD
HUNGARY
1047 Budapest, Baross u. 48-52.

Diagon Ltd.
Budapest, 20.05.2022

Signature: .....
Name of Authorized Signatory: Rózália Flórika-Katona
Position held in company: Deputy Managing Director

S.R.L. «DAC-SPECTRUMED»
IDNO 1002600042432
REPUBLICA MOLDOVA, mun. CHISINAU

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Appendix I.

Ref. No.	Product name	CE Registration No.
h20201	Diaton Diff. LMG Diluent	HU/CA01/20704/18
h20212	Dialyse-Diff-LMG	HU/CA01/20704/18
h24300	DiaTIMEPACK Reagents A120 CBC	HU/CA01/61084/15
h24301	Diabaso A120	HU/CA01/61084/15
h24302	DiaHgb A120	HU/CA01/61084/15
h24303	Dia-RBC/PLT A120	HU/CA01/61084/15
h24310	DiaDIFF TIMEPACK Reagents A120	HU/CA01/61084/15
h24311	DiaPerox-1 A120	HU/CA01/61084/15
h24312	DiaPerox-2 A120	HU/CA01/61084/15
h24313	DiaPerox-3 A120	HU/CA01/61084/15
h24314	Diaperox Sheath A120	HU/CA01/61084/15
h24315	Diaperox Sheath A120 PACK	HU/CA01/61084/15
h24321	DiaSheath Rinse A120	HU/CA01/61084/15
h24322	Diaretic Auto A120 PACK	HU/CA01/61084/15
h24332	Diaretic Auto A120	HU/CA01/61084/15
h24350	CBC DiaTimepack A120 CF	HU/CA01/61084/15
h24352	HGB Reag CF	HU/CA01/61084/15

FIRMA ȘTIINȚIFICĂ DE PRODUCȚIE
S.R.L.
«DAC-SPECTROMED»
IDNO 1002600042432
-2-
REPUBLICA MOLDOVA, mun. CHIȘINĂU

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DIAGON
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CE

Manufacturer 's Declaration of Conformity

Manufacturer's name: Diagon Ltd.

Manufacturer's registered place of business:
1047 Baross str. 48-52, Budapest, Hungary

declares in our own responsibility conformity of the products listed below as follows:

Haematology controls

according to the essential requirements Annex I of the Directive 98 / 79 / EC on in vitro diagnostic medical devices (IVD Directive):
The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (class: other IVD products), outside Annex II and not for self-testing of the Directive 98 / 79 / EC.

IVD Category: Non-listed according to IVDD (Others)

I declare that the use of the device(s) under appropriate conditions as described in product instructions of use will not compromise the health or safety of the patient, the user or other involved person.
I will ensure to institute and to keep up to date a quality system which enables me to review experiences gained from the device(s) in the post-production phase and to implement the necessary corrective actions.

Diagon Ltd.
Budapest, 11.11.2020.

Signature:
Name of Authorized Signatory: Rozália Flórika-Katona
Position held in company: Head of QA

DIAGON LTD. HUNGARY 1047 Budapest, Baross u. 48-52.

FIRMA ȘTIINȚIFICĂ DE PRODUCȚIE «DAC-SPECTROMED» IDNO 1002600042432 -2- REPUBLICA MOLDOVA, mun. CHIȘINĂU

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Product ID	Product name	CE Registration No.
DC7VL	D-Check 7 Low	HU/CA01/60076/14
DC7VN	D-Check 7 Normal	HU/CA01/60076/14
DC7VH	D-Check 7 High	HU/CA01/60076/14
DC18T2L	D-Check 18 Low	HU/CA01/60076/14
DC18T2N	D-Check 18 Normal	HU/CA01/60076/14
DC18T2H	D-Check 18 High	HU/CA01/60076/14
DC3TL	D-Check 3P Low	HU/CA01/60076/14
DC3TN	D-Check 3P Normal	HU/CA01/60076/14
DC3TH	D-Check 3P High	HU/CA01/60076/14
DCCD3RT1	D-Check CD3Ret	HU/CA01/60076/14
DCCD3RT2	D-Check CD3Ret	HU/CA01/60076/14
DCCD4KTL	D-Check CD4K Low	HU/CA01/60076/14
DCCD4KTN	D-Check CD4K Normal	HU/CA01/60076/14
DCCD4KTH	D-Check CD4K High	HU/CA01/60076/14
DCCD4RT1	D-Check CD4Ret	HU/CA01/60076/14
DCCD4RT2	D-Check CD4Ret	HU/CA01/60076/14
DCA120T1	D-Check A120 Ret	HU/CA01/60076/14
DCA120T2	D-Check A120 Ret	HU/CA01/60076/14
DCA120T3	D-Check A120 Ret	HU/CA01/60076/14
DC18PT2L	D-Check 18 Plus Low	HU/CA01/60076/14
DC18PT2N	D-Check 18 Plus Normal	HU/CA01/60076/14
DC18PT2H	D-Check 18 Plus High	HU/CA01/60076/14
DC18PTL	D-Check 18 Plus Low	HU/CA01/60076/14
DC18PTN	D-Check 18 Plus Normal	HU/CA01/60076/14
DC18PTH	D-Check 18 Plus High	HU/CA01/60076/14
DCSTL	D-check SYS Low	HU/CA01/60076/14
DCSTN	D-check SYS Normal	HU/CA01/60076/14
DCSTH	D-check SYS High	HU/CA01/60076/14
DCTTL	D-Chech Tech Low	HU/CA01/60076/14
DCTTN	D-Chech Tech Normal	HU/CA01/60076/14
DCTTH	D-Chech Tech High	HU/CA01/60076/14
DCXETL	D-Check XE Low	HU/CA01/60076/14
DCXETN	D-Check XE Normal	HU/CA01/60076/14
DCXETH	D-Check XE High	HU/CA01/60076/14
DC4KRTL	D-Check CD4KRet Low	HU/CA01/60076/14
DC4KRTN	D-Check CD4KRet Normal	HU/CA01/60076/14
DC4KRTH	D-Check CD4KRet High	HU/CA01/60076/14
DC5DTL	D-Check C5D Low	HU/CA01/60076/14
DC5DTN	D-Check C5D Normal	HU/CA01/60076/14
DC5DTH	D-Check C5D High	HU/CA01/60076/14
DCRETIV1	D-Check Ret-I 1V	HU/CA01/60076/14
DCRETIV2	D-Check Ret-I 2V	HU/CA01/60076/14
DCRETIV3	D-Check Ret-I 3V	HU/CA01/60076/14
DCRETIT1	D-Check Ret-I 1T	HU/CA01/60076/14
DCRETIT2	D-Check Ret-I 2T	HU/CA01/60076/14

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DCRETIT3	D-Check Ret-I 3T	HU/CA01/60076/14
DCRETP1	D-Check Ret P 1	HU/CA01/60076/14
DCRETP2	D-Check Ret P 2	HU/CA01/60076/14
DCRETP3	D-Check Ret P 3	HU/CA01/60076/14
DST1	D-Sed-Plus level 1	HU/CA01/60076/14
DST2	D-Sed-Plus level 2	HU/CA01/60076/14
DSV1	D-Sed-Plus level 1	HU/CA01/60076/14
DSV2	D-Sed-Plus level 2	HU/CA01/60076/14
DCALCD	D-Cal CD	HU/CA01/60076/14
DCALNEK	D-Cal NEK	HU/CA01/60076/14
DCALP	D-Cal Plus	HU/CA01/60076/14
DCALTECH	D-Cal TECH	HU/CA01/60076/14
DCXERET1	D-Check XE-RET Level 1	HU/CA01/60076/14
DCXERET2	D-Check XE-RET Level 2	HU/CA01/60076/14
DCXERET3	D-Check XE-RET Level 3	HU/CA01/60076/14
DCXENRBC1	D-Check XE-nRBC Level 1	HU/CA01/60076/14
DCXENRBC2	D-Check XE-nRBC Level 2	HU/CA01/60076/14
DCXENRBC3	D-Check XE-nRBC Level 3	HU/CA01/60076/14

FIRMA STIINTIFICA DE PRODUCERE S.R.L. «DAC-SPECTROMED» IDNO 1002600042432 -2- REPUBLICA MOLDOVA, mun. CHISINAU

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Manufacturer 's Declaration of Conformity

Manufacturer's name: **Diagon Ltd.**

Manufacturer's registered place of business:
1047 Baross str. 48-52, Budapest, Hungary

declares in our own responsibility conformity of the products listed in the **Appendix I.** below, according to the essential requirements Annex I of the Directive 98 / 79 / EC on *in vitro* diagnostic medical devices (IVD Directive):

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III (class: other IVD products) of the Directive 98 / 79 / EC, except of Point 6.

I declare that the use of the device(s) under appropriate conditions as described in product instructions of use will not compromise the health or safety of the patient, the user or other involved person.
I will ensure to institute and to keep up to date a quality system which enables me to review experiences gained from the device(s) in the post-production phase and to implement the necessary corrective actions.

Diagon Ltd.

Budapest, 12. 02. 2016.

DIAGON LTD HUNGARY 1047 Budapest, Baross u. 48-52.

Dr. Gabriella Áj
CEO

CE

FIRMA ȘTIINȚIFICĂ DE PRODUCȚIE S.R.L. «DAC-SPECTROMED» IDNO 1002600042432 -2- REPUBLICA MOLDOVA, mun. CHIȘINĂU

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Appendix I.

Item ID	Name	CE Reg. No.
	Control	
DDC18PT2,5L	D-Check D Plus 2,5L	HU/CA01/90613/15
DDC18PT2,5N	D-Check D Plus 2,5N	HU/CA01/90613/15
DDC18PT2,5H	D-Check D Plus 2,5H	HU/CA01/90613/15
DC3TL	D-Check 3P Low	HU/CA01/60076/14
DC3TN	D-Check 3P Normál	HU/CA01/60076/14
DC3TH	D-Check 3P High	HU/CA01/60076/14

FIRMA STIINTIFICĂ DE PRODUCȚIE S.R.L. «DAC SPECTROMED» IDNO 1002600042432 -2- REPUBLICA MOLDOVA, mun. CHIȘINĂU

DIAGON LTD HUNGARY 1047 Budapest, Baross u. 40-52.

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Manufacturer 's Declaration of Conformity

Manufacturer's name: **Diagon Ltd.**

Manufacturer's registered place of business:
1047 Baross str. 48-52, Budapest, Hungary

declares in our own responsibility conformity of the products listed in the **Appendix I.** below, according to the essential requirements Annex I of the Directive 98 / 79 / EC on *in vitro* diagnostic medical devices (IVD Directive):

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IVD Category: Non-listed according to IVDD (Others)

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I will ensure to institute and to keep up to date a quality system which enables me to review experiences gained from the device(s) in the post-production phase and to implement the necessary corrective actions.

Diagon Ltd.
Budapest, 25.05.2022

Signature: .....
Name of Authorized Signatory: Rozália Flórika-Katona
Position held in company: Deputy Managing Director

DIAGON LTD
HUNGARY
1047 Budapest, Baross u. 48-52.

«DAC-SPECTROMED» S.R.L.
IDNO 1002600042432
-2-
REPUBLICA MOLDOVA, mun. CHISINAU

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Appendix I.

Ref. No.	Product name	CE Registration No.
h31101, h31111	Dia-Diluent-D	HU/CA01/95421/15
h31102	Dia-Lyse-Diff D-CF	HU/CA01/95421/15

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