



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.
Budapest, 12.12.2022

Signature:
Name of Authorized Signatory:
Position held in company:



DIAGON LTD.
HUNGARY
Budapest, Baross u. 48-52
Rozália Flórika-Katona
Deputy Managing Director

Appendix I.

Ref. No.	Product name	CE Registration No.
DM-53D	DM-53D DILUENT	HU/CA01/95421/15
DM-53LEO I	DM-53 LEO I LYSE	HU/CA01/95421/15
DM-53LEO II	DM-53LEO II LYSE	HU/CA01/95421/15
DM-53LH	DM-53LH LYSE	HU/CA01/95421/15
DM-58 D	DM-58 D DILUENT	HU/CA01/95421/15
DM-58 LBA	DM-58 LBA LYSE	HU/CA01/95421/15
DM-58 LEO I	DM-58 LEO I LYSE	HU/CA01/95421/15
DM-58 LEO II	DM-58 LEO II LYSE	HU/CA01/95421/15
DM-58 LH	DM-58 LH LYSE	HU/CA01/95421/15
DM-68 FN	DM-68FN DYE	HU/CA01/95421/15
DM-68DR	DM-68DR DILUENT	HU/CA01/95421/15
DM-68DS	DM-68DS DILUENT	HU/CA01/95421/15
DM-68FD	DM-68FD DYE	HU/CA01/95421/15
DM-68FR	DM-68FR DYE	HU/CA01/95421/15
DM-68LB	DM-68LB LYSE	HU/CA01/95421/15
DM-68LD	DM-68LD LYSE	HU/CA01/95421/15
DM-68LH	DM-68LH LYSE	HU/CA01/95421/15
DM-68LN	DM-68LN LYSE	HU/CA01/95421/15
h12201	Diaton-CD 1.6 Diluent	HU/CA01/1973/20
h12203, h12213	Dialyse-CD 1.6	HU/CA01/1973/20
h12301	Diaton-CD 3/3.5 Diff.-Diluent	HU/CA01/1972/20
h12302	Diasheath-CD 3/3.5	HU/CA01/1972/20
h12305	Dialyse-VIC-CD 3.5	HU/CA01/1972/20
h12306	Diaret-prep.-CD 3.5	HU/CA01/1973/20
h12401	Diaton/Sheath-CD 4.0	HU/CA01/1972/20
h12402	Diaglobin-CD 4.0	HU/CA01/1972/20
h12403	Dialyse-CD 4.0 Part A	HU/CA01/1972/20
h12404	Dialyse-CD 4.0 Part B	HU/CA01/1972/20
h12501	DIATON-SHEATH-CD 3.2	HU/CA01/1973/20
h12502	DIALYSE-CD 3.2	HU/CA01/1973/20
h12503	DIAGLOBIN-CD 3.2	HU/CA01/1973/20
h15301	Diaton-CT-Diff. Diluent	HU/CA01/20704/18
h15309, h15339	Dialyse-CT-Diff-CF	HU/CA01/20704/18
h15310	DiaPack ACT Diff-CF	HU/CA01/20704/18
h15316	DiaPack M	HU/CA01/20704/18
h15416	Dia-Ret kit	HU/CA01/20704/18
h19201	Diaton-NK Diff. Diluent	HU/CA01/61676/15
h19202, h19212	Dialyse-NK Diff.	HU/CA01/61676/15
h19312, h19322	Dialyse-NK 5Diff	HU/CA01/61676/15

h20201	Diaton Diff. LMG Diluent	HU/CA01/20704/18
h20212	Dialyse-Diff-LMG	HU/CA01/20704/18
h20301P	Diadifton Argos/Pentra	HU/CA01/20704/18
h20312 P, h20322P	Dialyse-Argos Pentra	HU/CA01/20704/18
h20313/P	Dialyse-Baso II	HU/CA01/20704/18
h20313/P120	Dialyse-Baso 5Diff	HU/CA01/20704/18
h20314/P120	Diafix EO 5 Diff.P120	HU/CA01/20704/18
h20314/P60	Diafix EO 5 Diff.P60	HU/CA01/20704/18
h23101	Diaton-SYS Diluent	HU/CA01/29777/2019
h23105, h23125	Dialyser-SYS-SHB	HU/CA01/29777/2019
h23202	Diasheath-SYS	HU/CA01/29777/2019
h23225	Diastromlyser-SYS-3WP	HU/CA01/29777/2019
h23301	Diastromlyser-SYS-FD I	HU/CA01/29777/2019
h23302	Diastromlyser-SYS-FD II	HU/CA01/29777/2019
h23303	Diastromlyser-SYS-FBA	HU/CA01/29777/2019
h23401	Diastromlyser-SYS-WH	HU/CA01/29777/2019
h23601	Diastromlyser-SYS-4DL	HU/CA01/29777/2019
h23602	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	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
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
h28201	Abaton Diluent CF	HU/CA01/61676/15
h28212	Abalyse CF	HU/CA01/61676/15
h31101	Dia-Diluent-D	HU/CA01/95421/15

h31102	Dia-Lyse-Diff D-CF	HU/CA01/95421/15
h33101	Diaton 5D	HU/CA01/95421/15
h33102	Dialyse HB 5D	HU/CA01/95421/15
h33103	Dialyse BA 5D	HU/CA01/95421/15
h33104	Dialyse Diff I. 5D	HU/CA01/95421/15
h33105	Dialyse Diff II. 5D	HU/CA01/95421/15
h36501	Cellaton-5D	HU/CA01/12814/17
h36502	Cellalyse-BASO	HU/CA01/12814/17
h36503	Cellalyse-DIFF II	HU/CA01/12814/17
h36504	Cellalyse-DIFF I	HU/CA01/12814/17
h73101	Cellaton-D	HU/CA01/32599/20
h73102	Cellalyse	HU/CA01/32599/20
h24101	Hemoglobin Reagent	HU/CA01/61084/15
h24102	Perox Dil. 3	HU/CA01/61084/15
h24103	RBC/PLT Dil.	HU/CA01/61084/15
h24104	Perox Dil. 2	HU/CA01/61084/15
h24105	Baso Dil.	HU/CA01/61084/15
h24106	Perox Dil. 1	HU/CA01/61084/15
h24107, h24117, h24127	Perox Sheath	HU/CA01/61084/15
h24109, h24119, h24129	RBC/Baso Sheath	HU/CA01/61084/15
h24122	Defoamer	HU/CA01/61084/15
h24100	Reagent Pack	HU/CA01/61084/15
24200	Reagent Pack CF	HU/CA01/61084/15