

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, 04. 03. 2016.



Appendix I.

Item ID	Name	CE Reg. No.
	Coagulation	
82024	Dia-PT LIQUID	HU/CA01/58869/15
	Haematology	
h28101	Abacus Abaton	HU/CA01/61676/15
h28102	Abacus Abalyse	HU/CA01/61676/15
h28112	Abacus Abalyse	HU/CA01/61676/15
h28103	Abacus Abaclean	HU/CA01/61676/15
h28113	Abacus Abaclean	HU/CA01/61676/15
h23101	Diaton-SYS Diluent	HU/CA01/61096/15
h23401	Diastromlyser-SYS-WH	HU/CA01/61096/15
h23126	Diaclean-SYS	HU/CA01/61096/15
h12501	DIATON-SHEATH-CD 3.2	HU/CA01/61075/15
h12502	DIALYSE-CD 3.2	HU/CA01/61075/15
h12503	DIAGLOBIN-CD 3.2	HU/CA01/61075/15
h50111	CELL CLENZ	HU/CA01/61075/15
h12301	Diaton-CD 3/3.5 Diff.	HU/CA01/61075/15
h12302	Diasheath-CD 3/3.5	HU/CA01/61075/15
h12303	Dia-Rinse-CD 3.5	HU/CA01/61075/15
h12305	Dialyse-VIC-CD 3.5	HU/CA01/61075/15
h20212	Dialyse-Diff-LMG	HU/CA01/61093/15

