



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:

Coagulation reagents (Appendix I)

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, 26.05.2022.

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


Rozália Flórika-Katona
Deputy Managing Director



Appendix I. Coagulation reagents

81050	Dia-PT5	HU/CA01/32864/22
81025	Dia-PT5	HU/CA01/32864/22
81100	Dia-PT 10	HU/CA01/32864/22
82012	Dia-PT LIQUID	HU/CA01/32864/22
82024	Dia-PT LIQUID	HU/CA01/32864/22
82048	Dia-PT LIQUID	HU/CA01/32864/22
82096	Dia-PT LIQUID	HU/CA01/32864/22
83050	Dia-PT R	HU/CA01/32864/22
83100	Dia-PT R	HU/CA01/32864/22
71048	Dia-PTT	HU/CA01/32864/22
71030	Dia-PTT	HU/CA01/32864/22
72012	Dia-PTT LIQUID	HU/CA01/32864/22
72024	Dia-PTT LIQUID	HU/CA01/32864/22
72048	Dia-PTT LIQUID	HU/CA01/32864/22
51036	Dia-TT	HU/CA01/32864/22
61060	Dia-FIB	HU/CA01/32864/22
61024	Dia-FIB 2	HU/CA01/32864/22
91010	Dia-CONT I-II	HU/CA01/32864/22
91020	Dia-CONT I-II	HU/CA01/32864/22
95012	Dia-CAL	HU/CA01/32864/22
86025	Coag S INR TEST KIT	HU/CA01/32864/22
86010	Coag S INR TEST KIT	HU/CA01/32864/22
33012	Dia-AT III (FIIa)	HU/CA01/32864/22
32075	Dia-D-DIMER	HU/CA01/32864/22
93010	Dia-CONT Ddi I-II	HU/CA01/32864/22
93020	Dia-CONT Ddi I-II	HU/CA01/32864/22
38005	Dia-DEF II	HU/CA01/32864/22
38105	Dia-DEF V	HU/CA01/32864/22
38205	Dia-DEF VII	HU/CA01/32864/22
38505	Dia-DEF X	HU/CA01/32864/22
38305	Dia-DEF VIII	HU/CA01/32864/22
38405	Dia-DEF IX	HU/CA01/32864/22
38605	Dia-DEF XI	HU/CA01/32864/22
38705	Dia-DEF XII	HU/CA01/32864/22
34105	Dia-LA Screen	HU/CA01/32864/22
34104	Dia-LA Confirm	HU/CA01/32864/22
34105	Dia-LA CONT P	HU/CA01/32864/22

37208	Dia-PS Clot	HU/CA01/32864/22
37310	Dia-APC-R-Clot	HU/CA01/32864/22
37106	Dia-PC Chrom	HU/CA01/32864/22
01036	Dia-AT III	HU/CA01/12591/09
95112	Dia-CAL AT III	HU/CA01/12591/09
90112	Dia-MULTI N	HU/CA01/12804/09
90212	Dia-MULTI P	HU/CA01/12804/09
09305	Dia-CONT Spec N	HU/CA01/24024/14
09405	Dia-CONT Spec P	HU/CA01/24024/14
09605	Dia-CAL Spec	HU/CA01/24024/14

