



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.

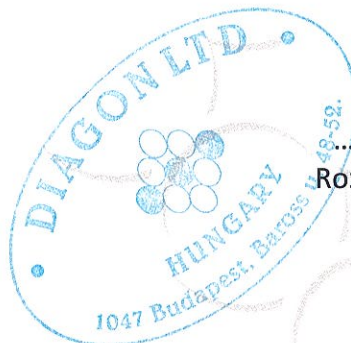
IVD Category: Non-listed according to IVDD (Others)

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:
Position held in company:




Rozália Flórika-Katona
Head of QA

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
DC4KR TN	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

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