



Manufacturer's Declaration of Conformity

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

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 Kft.

Budapest, 2.11.2021

Signature:

Name of Authorized Signatory:

Position held in company:



Rozália Flóríka-Katona

Rozália Flóríka-Katona

Head of QA and Regulatory Affairs

Appendix I.

Product ID	Product name	CE Reg. No.
DDC-18T1 L	D-Check D 1L	HU/CA01/1872/17
DDC-18T1 N	D-Check D 1N	HU/CA01/1872/17
DDC-18T1 H	D-Check D 1H	HU/CA01/1872/17
DDC-18T2 L	D-Check D L	HU/CA01/1872/17
DDC-18T2 N	D-Check D N	HU/CA01/1872/17
DDC-18T2 H	D-Check D H	HU/CA01/1872/17
DDC-18T2,5 L	D-Check D 2,5L	HU/CA01/1872/17
DDC-18T2,5 N	D-Check D 2,5N	HU/CA01/1872/17
DDC-18T2,5 H	D-Check D 2,5H	HU/CA01/1872/17
DDC-18T3 L	D-Check D 3L	HU/CA01/1872/17
DDC-18T3 N	D-Check D 3N	HU/CA01/1872/17
DDC-18T3 H	D-Check D 3H	HU/CA01/1872/17
DDC-18T4 L	D-Check D 4L	HU/CA01/1872/17
DDC-18T4 N	D-Check D 4N	HU/CA01/1872/17
DDC-18T4 H	D-Check D 4H	HU/CA01/1872/17
DDC18PT2L	D-Check D Plus L	HU/CA01/1872/17
DDC18PT2N	D-Check D Plus N	HU/CA01/1872/17
DDC18PT2H	D-Check D Plus H	HU/CA01/1872/17
DDC18PT2,5L	D-Check D Plus 2,5L	HU/CA01/1872/17
DDC18PT2,5N	D-Check D Plus 2,5N	HU/CA01/1872/17
DDC18PT2,5H	D-Check D Plus 2,5H	HU/CA01/1872/17
DDC18PT3L	D-Check D Plus 3L	HU/CA01/1872/17
DDC18PT3N	D-Check D Plus 3N	HU/CA01/1872/17
DDC18PT3H	D-Check D Plus 3H	HU/CA01/1872/17
DDC18PT4L	D-Check D Plus 4L	HU/CA01/1872/17
DDC18PT4N	D-Check D Plus 4N	HU/CA01/1872/17
DDC18PT4H	D-Check D Plus 4H	HU/CA01/1872/17
DDC5DT3L	D-Check 5Diff 3 ml L	HU/CA01/1872/17
DDC5DT3N	D-Check 5Diff 3 ml N	HU/CA01/1872/17
DDC5DT3H	D-Check 5Diff 3 ml H	HU/CA01/1872/17
DDC5DT4,5L	D-Check 5Diff 4,5 ml L	HU/CA01/1872/17
DDC5DT4,5N	D-Check 5Diff 4,5 ml N	HU/CA01/1872/17
DDC5DT4,5H	D-Check 5Diff 4,5 ml H	HU/CA01/1872/17
DDC5DPT3L	D-Check 5Diff Plus 3ml L	HU/CA01/1872/17
DDC5DPT3N	D-Check 5Diff Plus 3ml N	HU/CA01/1872/17
DDC5DPT3H	D-Check 5Diff Plus 3ml H	HU/CA01/1872/17
DDC5DPT4,5L	D-Check 5Diff Plus 4,5ml L	HU/CA01/1872/17

Product ID	Product name	CE Reg. No.
DDC5DPT4,5N	D-Check 5Diff Plus 4,5ml N	HU/CA01/1872/17
DDC5DPT4,5H	D-Check 5Diff Plus 4,5ml H	HU/CA01/1872/17
DCALD3,0	D-Cal D	HU/CA01/1872/17
DCALD4,5	D-Cal D	HU/CA01/1872/17
DDCRNR3C1	D-Check RET+NR 3 ml CONTROL 1	HU/CA01/1872/17
DDCRNR3C2	D-Check RET+NR 3 ml CONTROL 2	HU/CA01/1872/17
DDCRNR3C3	D-Check RET+NR 3 ml CONTROL 3	HU/CA01/1872/17
DDCRNR4,5C1	D-Check RET+NR 4,5 ml CONTROL 1	HU/CA01/1872/17
DDCRNR4,5C2	D-Check RET+NR 4,5 ml CONTROL 2	HU/CA01/1872/17
DDCRNR4,5C3	D-Check RET+NR 4,5 ml CONTROL 3	HU/CA01/1872/17

