

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, 12. 02. 2016.

Dr. Gabriella Áj
CEO



Appendix I.

Item ID	Name	CE Reg. No.
	Control	
DDC18PT2,5L	D-Check D Plus 2,5L	HU/CA01/90613/15
DDC18PT2,5N	D-Check D Plus 2,5N	HU/CA01/90613/15
DDC18PT2,5H	D-Check D Plus 2,5H	HU/CA01/90613/15
DC3TL	D-Check 3P Low	HU/CA01/60076/14
DC3TN	D-Check 3P Normál	HU/CA01/60076/14
DC3TH	D-Check 3P High	HU/CA01/60076/14