DIAGON
Solutions beyond imagination

CE

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.

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, 13.03.2023

DIAGON LTD
1047 Budapest, Baross u. 48-52.
HUNGARY

Signature: .....
Name of Authorized Signatory: Levente Szén
Position held in company: Head of QA

SGS SGS SGS Diagon Ltd. - Hungary 1047 Budapest, Baross u. 48-52. 1325 Újpest, Pf.41 tel.: (+36 1) 369 6500 fax: (+36 1) 369 6301 e-mail: diagon@diagon.com www.diagon.com

DIAGON
Solutions beyond imagination

Appendix I.

Ref. No.	Product name	CE Registration No.
h30101	Diaton Erma Diluent	HU/CA01/61676/15
h30102	Diadriplyse-Erma	HU/CA01/61676/15
h30103	Dialyse Erma	HU/CA01/61676/15
h30109	Dialyse ERMA CF	HU/CA01/61676/15

SGS SGS SGS **Diagon Ltd. - Hungary** 1047 Budapest, Baross u. 48-52. 1325 Újpest, Pf.41 tel.: (+36 1) 369 6500 fax: (+36 1) 369 6301 e-mail: diagon@diagon.com www.diagon.com