

DIAGON Kft.

H-1047 Budapest, Baross u. 48-52.

Has been assessed under the management system of the certified organisation defined in the main certificate HU10/5084 as meeting the requirements of

MSZ EN ISO 13485:2016

For the following activities

Design and development, production and sales of hematology-, hemostasis reagent, hematology-, hemostasis control and calibrator. Design and development, production, sales and service of in vitro diagnostic instruments for hematology and hemostasis. Own branding manufacture and sales of hemostasis reagent, hematology-, hemostasis control and calibrator, hematology in vitro diagnostic instruments. Distribution and sales of other non-active laboratory medical devices. Sales and service of other in vitro diagnostic instruments.

This certificate is valid from 18 January 2024 until 17 January 2027 and remains valid subject to satisfactory surveillance audits. Issue 2.

The validity of this certificate depends on the validity of the main certificate.

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by Andras Tohl

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This is a translation of the certificate HU10/5084.03, continued

DIAGON Kft.



MSZ EN ISO 13485:2016

Issue 2

Sites

DIAGON Kft.

H-1047 Budapest, Baross u. 48-52.

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DIAGON Kft.

H-1044 Budapest, Óradna u. 4.

Design and development, production of in vitro diagnostic instruments for hematology and hemostasis.

DIAGON Kft.

H-1044 Budapest, Ezred u. 1-3.

Warehousing and distribution activity in support of Design and development, production and sales of hematology-, hemostasis reagent, hematology-, hemostasis control and calibrator. Design and development, production, sales and service of in vitro diagnostic instruments for hematology and hemostasis. Own branding manufacture and sales of hemostasis reagent, hematology-, hemostasis control and calibrator, hematology in vitro diagnostic instruments. Distribution and sales of other nonactive laboratory medical devices. Sales and service of other in vitro diagnostic instruments.





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