DIAGON®
Solutions beyond imagination

EU DECLARATION OF CONFORMITY

WE THE MANUFACTURER

Name	**DIAGON Kft.**
Address	Baross u. 48-52. Budapest H-1047 Hungary
Single Registration Number (SRN)	HU-MF-000023582

TAKE SOLE RESPONSIBILITY FOR AND HEREBY DECLARE THAT THE PRODUCT(S)

Device category	AUTOMATED COAGULOMETERS
Basic UDI-DI	599279506WT
Country of origin	Hungary
Legal manufacturer	DIAGON Kft.
Intended Purpose	Coag M is a fully automated blood coagulation analyser and for in vitro diagnostic use only. The primary test specimen is plasma separated with centrifugation from sodium-citrate anticoagulated human whole blood. Any other use should be considered as non-intended. The instrument can analyse samples using coagulation, chromogenic and immunoassay methods. The analysed data can be stored, displayed and reported. The instrument has several built-in functions, including automatic reagent handling by barcode system, priority processing of STAT samples and quality control. Risk of providing erroneous results and/or damage of the instrument is substantially reduced with exclusive use of reagents, cleaners and cuvettes.

Related device(s)	Product name	Reference number
	Coag M automated coagulometer	**g-CoagM**

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MEET(S) THE PROVISIONS OF THE FOLLOWING DIRECTIVES, REGULATIONS AND STANDARDS AND COMMON SPECIFICATIONS

Regulation(s)	IVDR (EU) 2017/746 on in vitro diagnostic medical devices	
Risk Class	A ☒ B ☐ C ☐ D ☐	
IVDR conformity assessment route	☒ ANNEX II + ANNEX III + ANNEX IV (Class A devices excluding sterile devices)	
	☐ ANNEX II + ANNEX III + ANNEX IV + ANNEX IX (Chapter I & III) + ANNEX XI (Class A sterile devices)	
	☐ ANNEX IX (Chapter I & III, II section 4) + ANNEX IV (Class B & C devices excluding self-testing and near patient testing devices)	EU Certificate N/A
		Notified Body (NB) N/A
		NB Number N/A
	☐ANNEX IX (Chapter I & III, II section 4 & 5.1) + ANNEX IV (Class B & C self-testing and near patient testing devices)	EU Certificate N/A
		Notified Body (NB) N/A
		NB Number N/A
	☐ ANNEX IX (Chapter I & III, II including section 4.9) + ANNEX IV (Class D devices)	EU Certificate N/A
		Notified Body (NB) N/A
		NB Number N/A
Directive(s)	2011/65/EU - Amended by 2015/863/EU – ROHS Device Category: 8 – Medical Devices 2004/108/EC – Electromagnetic compatibility 2014/35/EU Annex I.	
Standard(s)	EN 61010-1:2010; IEC 61010-2-101:2015; EN 61010-2-81:2015, EN 61326-1:2013; EN 61326-2-6:2013	
Common Specification(s)	Not Applicable	

Budapest, 25 May 2022

DIAGON LTD
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