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	599279515WU
Country of origin	Hungary
Legal manufacturer	DIAGON Kft.
Intended Purpose	Coag XL / Coag XL CP is a fully automated blood coagulation analyser. The instrument can analyse decalcified plasma 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. A cap piercer unit can be installed as a factory option (XL without, XL CP with cap piercer unit). For In Vitro Diagnostic use only.

	Product name	Reference number
Related device(s)	**Coag XL automated coagulometer**	**g-CoagXL**
	Coag XL automated coagulometer with cap piercer	**g-CoagXLCP**

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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	
Standard(s)	EN 61010-1:2001, EN 61010-2-101:2002 EN 61326-1:2006; EN 61326-2-6:2006, EN 61000-3-3:2008	
Common Specification(s)	Not Applicable	

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DIAGON LTD
HUNGARY
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