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	SEMI-AUTOMATED COAGULOMETERS
Basic UDI-DI	599279504WP
Country of origin	Hungary
Legal manufacturer	DIAGON Kft.
Intended Purpose	Coag 4D / Coag 4D D-Dimer / Coag 4D Plus are a 4-channel semi-automated blood coagulation analysers. The instruments can analyse decalcified plasma samples using coagulation, chromogenic and immunoassay methods. The analysed data can be stored, displayed and reported. The instruments has several functions, including built-in thermal printer and connectivity to use automatic reagent handling by barcode system. The immunoassay measuring capability can be installed by activation (4D without, 4D D-Dimer, 4D Plus with immunoassay method).For In Vitro Diagnostic use only.

	Product name	Reference number
Related device(s)	**Coag 4D Coagulometer**	**g-Coag4Dm**
	Coag 4D coagulometer D-Dimer	**g-Coag4DDi**
	Coag 4D Plus coagulometer	**g-Coag4Dplus**

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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)	Coag 4D / Coag 4D D-Dimer / Coag 4D Plus: 2011/65/EU - Amended by 2015/863/EU – ROHS Device Category: 8 – Medical Devices Coag 4D / Coag 4D D-Dimer: 2004/108/EC – Electromagnetic compatibility Coag 4D Plus: 2014/30/EU – Electromagnetic compatibility	
Standard(s)	Coag 4D / Coag 4D D-Dimer: EN 61010-1:2001; EN 61010-2-101:2002; IEC 61326-2-6:2005 Coag 4D Plus: IEC 61010-1:2010+AMD1:2016; IEC 61010-2-101:2015; EN 61326-1:2013; EN 61326-2-6:2013	
Common Specification(s)	Not Applicable	

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DIAGON LTD
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