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	BUFFERS (HAEMOSTASIS)
Basic UDI-DI	599279121W3
Country of origin	Hungary
Legal manufacturer	DIAGON Kft.
Intended Purpose	Dia-IMIDAZOL is dilution buffer used as diluting control, calibrator and human sample when performing coagulation tests in decalcified plasma on coagulometry assay, for all human populations. For In Vitro Diagnostic use only.

Related device(s)	Product name	Reference number
	Dia-IMIDAZOL	**21180**

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

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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)	N/A	
Standard(s)	N/A	
Common Specification(s)	N/A	

Budapest, 25 May 2022

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

Dr. József Kern
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