

## EU DECLARATION OF CONFORMITY

### WE THE MANUFACTURER

Name	<b>DIAGON Kft.</b>
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	CALCIUM CHLORIDE
Basic UDI-DI	599279141W9
Country of origin	Hungary
Legal manufacturer	DIAGON Kft.
Intended Purpose	Dia-CaCl <sub>2</sub> is a 0,025M buffered solution of calcium chloride used as supplementary reagent for various 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
	<b>Dia-CaCl<sub>2</sub></b>	<b>41048</b>
	<b>Dia-CaCl<sub>2</sub></b>	<b>41192</b>

**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 <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>	
IVDR conformity assessment route	<input checked="" type="checkbox"/> ANNEX II + ANNEX III + ANNEX IV (Class A devices excluding sterile devices)	
	<input type="checkbox"/> ANNEX II + ANNEX III + ANNEX IV + ANNEX IX (Chapter I & III) + ANNEX XI (Class A sterile devices)	
	<input type="checkbox"/> 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
	<input type="checkbox"/> 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		
<input type="checkbox"/> 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


  
**Dr. József Kern**  
 Managing Director