DECLARATION OF CONFORMITY



Product name / Trade name	IDS-iSYS System Liquid (Syst.I)	REF IS-CS100	
Product name / Trade name	i-Track 10 System Liquid	REF TD IS-CS100	
Product name / Trade name	System Liquid 5L	REF 41404	
BASIC UDI-DI: 5425030421017RC	GMDN: 59058	EMDN: W0201020185	
Immunodiagnostic Systems SA 101 Rue Ernest Solvay B-4000 Liege Belgium			
SINGLE REGISTRATION NUMBER: BE-MF-000015341			
RISK CLASS:	⊠A □B □C	□Þ	
CLASSIFICATION RULE (ANNEX VIII): Rule 5(a)			
CONFORMITY ROUTE:	☐ ANNEX IX Full Quality System (Class B, C & D)		
CE Marking Date:	20th May 2022		
COMMON SPECIFICATIONS:	Not Applicable		
We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives Regulation EU 2017/746 on <i>In vitro</i> Diagnostic Medical Devices			
Date: 15/Jun/2022 Sign	0.13		
Place: Belgium K Simonis QA Officer			
Date: 15/Jun/2022 Sign	Signed on behalf of Immunodiagnostic Systems SA		
/ -/	J.Moor Senior QA Manager		

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