


DECLARATION OF CONFORMITY



Product name / Trade name	<input type="checkbox"/> REF IS-10DB	BASIC UDI-DI: 5060169691100W7
IDS-iSYS Diluent B	GMDN: 58237	EMDN: W0201020185
	<input type="checkbox"/> EC	<input type="checkbox"/> REP
Immunodiagnostic Systems Limited, 10 Didcot Way, Baldon Business Park, Baldon, Tyne and Wear, NE35 9PD, UK	Immunodiagnostic Systems SA 101 Rue Ernest Solvay B-4000 Liege Belgium	
SINGLE REGISTRATION NUMBER: GB-MF-000015851	SINGLE REGISTRATION NUMBER: BE-AR-000015342	

RISK CLASS: A B C D

CLASSIFICATION RULE (ANNEX VIII) :

CONFORMITY ROUTE: ANNEX IX Full Quality System (Class B, C & D)
 ANNEX I & II+III (non-sterile Class A)

CE Marking Date: 23rd 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 *In vitro* Diagnostic Medical Devices

Date: 23rd May 2022

Signed on behalf of Immunodiagnostic Systems Limited

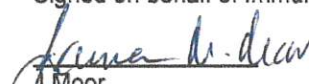
Place: UK


M Henderson
RA Manager

Date: 23rd May 2022

Signed on behalf of Immunodiagnostic Systems Limited

Place: UK


J Moor
Senior QA Manager - International