DECLARATION OF CONFORMITY

Product name / Trade name	REF IS-10DB	BASIC UDI-DI: 5060169691100W7
IDS-iSYS Diluent B	GMDN: 58237	EMDN: W0201020185

	EC REP
Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne and Wear, NE35 9PD, UK SINGLE REGISTRATION NUMBER: GB-MF-000015851	Immunodiagnostic Systems SA 101 Rue Ernest Solvay B-4000 Liege Belgium 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

Place: UK

Signed on behalf of Immunodiagnostic Systems Limited

M Henderson
RA Manager

Date: 23rd May 2022

Place: UK

Signed on behalf of Immunodiagnostic Systems Limited

J Moor
Senior QA Manager - International

Ver.07