DECLARATION OF CONFORMITY

Product name / Trade name	IDS-iSYS Cuvettes	REF IS-CC100
Product name / Trade name	Reaction cuvette	REF TD IS-CC100
BASIC UDI-DI: 5060169693975YU	**GMDN:** 61032	**EMDN:** W05030199

Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne and Wear, NE35 9PD, UK SINGLE REGISTRATION NUMBER: GB-MF-000015851	EC REP 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) : Rule 5b

CONFORMITY ROUTE: ☐ ANNEX IX Full Quality System (Class B, C & D)

☒ ANNEX I & II+III *(non-sterile Class A)*

CE Marking Date: **25 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
- Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH)

Date: 25 May 2022 Signed on behalf of Immunodiagnostic Systems France SAS

Place: Pouilly en Auxois

Anne SEIGNEZ
Quality & RA Manager

Date: 26 MAY 2022 Signed on behalf of Immunodiagnostic Systems Limited

Place: UK

Mick HENDERSON
RA Manager

Ver.07