DECLARATION OF CONFORMITY

Product name / Trade name	REF IS-5130	BASIC UDI-DI: 5060169690738XP
IDS-iSYS 17-OH Progesterone Control Set	GMDN: 45709	EMDN: W0102152008
Intended Purpose	For *In Vitro* Diagnostic Use. For Laboratory Professional Use. The IDS-iSYS 17-OH Progesterone Control Set is for in vitro diagnostic use, for the quality control of the IDS-iSYS 17-OH Progesterone on the IDS System.	

	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) : Rule 6; Implementing rule 1.6

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

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

Name of the Notified Body / Identification: TÜV Rheinland LGA Products GmbH 0197

CE Marking Date: **23rd June 2026**

EU CERTIFICATE No.: **HX 2333083-1**

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 June 2026

Place: UK

Signed on behalf of Immunodiagnostic Systems Limited

M Henderson
Group RA Manager & PRRC

Date: 23rd June 2026

Place: UK

Signed on behalf of Immunodiagnostic Systems Limited

Mohammed Adil
RA Manager (Specialist)

Ver.06