DECLARATION OF CONFORMITY

Product name / Trade name	REF IS-5300	BASIC UDI-DI: 5060169691230WM
IDS-iSYS Free Testosterone	GMDN: 63762	EMDN: W0102050110
Intended Purpose	For In Vitro Diagnostic Use For Laboratory Professional Use The IDS-iSYS Free Testosterone assay is an in vitro diagnostic device intended for the quantitative determination of free testosterone in human serum or plasma on the IDS System. Results are to be used in conjunction with other clinical and laboratory data as an aid in the diagnosis and monitoring of disorders involving the male sex hormones (androgens) in the paediatric and adult population.	

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 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)

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