DECLARATION OF CONFORMITY

Product name / Trade name	REF IS-5400	BASIC UDI-DI: 5060169691261WY
IDS Androstenedione	GMDN: 54068	EMDN: W0102050101
Intended Purpose	For In Vitro Diagnostic Use For Laboratory Professional Use IDS Androstenedione assay is an automated *in vitro* diagnostic device intended for the quantitative determination of androstenedione in human serum on the IDS system. Results are to be used in conjunction with other clinical and laboratory data as an aid in the diagnosis of androgen disorders in adult and pediatric populations.	

	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

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: **30th October 2023**

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: 15th April 2024

Place: UK

Signed on behalf of Immunodiagnostic Systems Limited

M Henderson
RA Manager & PRRC

Date: 15th April 2024

Place: UK

Signed on behalf of Immunodiagnostic Systems Limited

D. Mullington
Group QA/RA Director & PRRC

Ver.02