# DECLARATION OF CONFORMITY

| Product name / Trade name | REF IS-5420 | BASIC UDI-DI: 5060169691261WY |
|---|---|---|
| IDS Androstenedione Calibrator Set | GMDN: 41779 | EMDN: W0102152208 |
| Intended Purpose | For In Vitro Diagnostic Use<br>For Laboratory Professional Use<br>The IDS Androstenedione Calibrator Set is used for the calibration of IDS Androstenedione on the IDS system. | |

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