


## DECLARATION OF CONFORMITY



<b>Product name / Trade name</b>		<b>REF</b> IS-4520NG	<b>BASIC UDI-DI:</b> 5060169696457YN
IDS ACTH II Calibrator Set		<b>GMDN:</b> 41795	<b>EMDN:</b> W0102152208
<b>Intended Purpose</b>	For In Vitro Diagnostic Use For Laboratory Professional Use The IDS ACTH II Calibrator Set is used for the calibration of the IDS ACTH II assay on the IDS system.		
	<b>EC</b> <b>REP</b>		
Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne and Wear, NE35 9PD, UK		Immunodiagnostic Systems SA 101 Rue Ernest Solvay B-4000 Liege Belgium	
SINGLE REGISTRATION NUMBER: GB-MF-000015851		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:**30<sup>th</sup> 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: 15<sup>th</sup> April 2024

Signed on behalf of Immunodiagnostic Systems Limited

Place: UK

  
M Henderson  
RA Manager & PRRCDate: 15<sup>th</sup> April 2024

Signed on behalf of Immunodiagnostic Systems Limited

Place: UK

  
D. Mullington  
Group QA/RA Director & PRRC