

## DECLARATION OF CONFORMITY



<b>Product name / Trade name</b>	IDS-iSYS D-Sorb Solution	REF	IS-DS200
<b>Product name / Trade name</b>	i-Track <sup>10</sup> D-Sorb Solution Set	REF	TD IS-DS200
<b>Product name / Trade name</b>	ZENIT RA D-Sorb Solution	REF	41436
<b>BASIC UDI-DI: 5060169692305X2</b>	<b>GMDN: 59058</b>	<b>EMDN: W0201020185</b>	
		EC	REP
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 5(a)

**CONFORMITY ROUTE:**

ANNEX IX Full Quality System  
(Class B, C & D)

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

**CE Marking Date:** 23<sup>rd</sup> May 2022

**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: 20 June 2022

Place: UK

Signed on behalf of Immunodiagnostic Systems Limited

M Henderson  
RA Manager

Date: 20 Jun 2022

Place: UK

Signed on behalf of Immunodiagnostic Systems Limited

J Moor  
Senior QA Manager