


DECLARATION OF CONFORMITY



Product name / Trade name	IDS Immucleaner	REF	IS-IM100
Product name / Trade name	i-Track ¹⁰ Immucleaner	REF	TD IS-IM100
BASIC UDI-DI: 5060169693906Y9	GMDN: 59058	EMDN: W0201020185	
	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: 23rd 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 Signed on behalf of Immunodiagnostic Systems Limited

Place: UK 
M Henderson
RA Officer

Date: 20 Jun 2022 Signed on behalf of Immunodiagnostic Systems Limited

Place: UK 
J Moor
Senior QA Manager