


DECLARATION OF CONFORMITY



Product name / Trade name	IDS-iSYS Cartridge Check System (CCS)	REF	IS-6010
Product name / Trade name	i-Track ¹⁰ Cartridge Check System	REF	TD IS-6010
Product name / Trade name	Cartridge Check System	REF	41401
BASIC UDI-DI: 5425030426012S5	GMDN: 65954	EMDN: W0102152099	
 Immunodiagnostic Systems SA 101 Rue Ernest Solvay B-4000 Liege Belgium SINGLE REGISTRATION NUMBER: BE-MF-000015341			

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: 20th May 2022

COMMON SPECIFICATIONS: Not Applicable

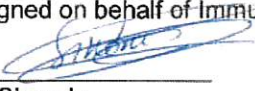
We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives

- Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices

Date: 01/Aug/2022

Signed on behalf of Immunodiagnostic Systems Limited


Place: Belgium


K Simonis
QA Officer

Date: 01/Aug/2022

Signed on behalf of Immunodiagnostic Systems Limited

Place: UK


M Henderson
RA Manager