


DECLARATION OF CONFORMITY



Product name / Trade name	IDS-iSYS Trigger Set	REF	IS-CT100
Product name / Trade name	i-Track 10 Trigger Set	REF	TD IS-CT100
Product name / Trade name	Trigger Set	REF	41403
BASIC UDI-DI: 5425030421024R9	GMDN: 61163	EMDN:	W0201020185
 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

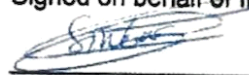
We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives

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

Date: 15/Jun/2022

Signed on behalf of Immunodiagnostic Systems SA

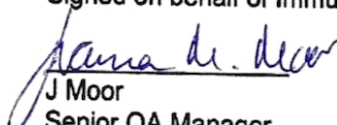
Place: Belgium


K Simonis
QA Officer

Date: 15/Jun/2022

Signed on behalf of Immunodiagnostic Systems SA

Place: UK


J Moor
Senior QA Manager