immunodiagnostic systems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 23640:2015, BS EN ISO 18113-2:2011, BS EN ISO 15223-1: 2016
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	Urine CrossLaps® (CTX-I) EIA (Cat. No. AC-03F1)
GMDN Code:	53640
CE Marking:	01st December 2003
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020

Signed on behalf of Immunodiagnostic Systems Limited:

Mick Henderson
Regulatory Affairs Manager

Date: 05 November 2020

Signed on behalf of Immunodiagnostic Systems Limited:

Jessica Oxley
Regulatory Affairs Officer

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