LORNE LABORATORIES LIMITED	Document Title:	**EU Declaration of Conformity**
Date Effective: **02 Oct 2019**	Document Number:	**DoC470**
DCN: **999**	Revision Number:	**01**

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product Name	Catalogue Numbers	GMDN Code
LISS Ready for Use	470020 and 470250	52718

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of the European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009 and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

The Intended Purpose of this product is the potentiation of antibody-antigen reactions in blood group serology which should be only be carried out by suitably trained professionals.

The manufacturer of this product is Lorne Laboratories Ltd who is located at:

Address line 1: Unit 1 Cutbush Park Industrial Estate
Address line 2: Danehill
City: Lower Earley
County: Berkshire
Postal code: RG6 4UT
Country: United Kingdom
Telephone number: +44-(0)118 921 2264
Fax number: +44-(0)118 986 4518
Website: www.lornelabs.com
DUNS Number: 732670703

and is in conformity with the national standards transposing harmonised standards:

- BS EN ISO 13485:2016
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

Lorne's EU Authorised Representative is "Advena Limited" residing at Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta.

Digitally signed by Ceaicovschi Tudor
Date: 2022.11.07 09:04:36 EET
Reason: MoldSign Signature
Location: Moldova

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This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 02 October 2019.

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Eddy Velthuis
Technical Director