

EC DECLARATION OF CONFORMITY

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

Product Name	Catalogue Number
LISS Ready For Use	470020
	470250
	470025

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 Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This product has been manufactured by Lorne Laboratories Ltd at their facilities which are located at:

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Postal code: RG6 4UT
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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.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 10 April 2019.



Eddy Velthuis
Technical Director