



## UKCA Declaration of Conformity for LumiraDx INR Quality Controls (S-RA-TEC-0003)

Document Number:	S-RA-REP-00461	Revision:	1
Information Classification	Public		



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## UK Declaration of Conformity for LumiraDx INR Quality Controls (EN)

We, the legal manufacturer, as stated below, hereby declares under our sole responsibility,

<b>Legal Manufacturer:</b>	LumiraDx UK Ltd.
<b>Address:</b>	Dumyat Business Park, Alloa FK10 2PB, United Kingdom

that the identified products to which this declaration relates,

Identification	
<b>Product Name</b>	LumiraDx INR Quality Controls
<b>Catalogue Numbers</b>	L0030801nnxxx (where nn represents two digits corresponding to language variants, and where xxx represents three digits corresponding to number of units the catalogue number contains).
<b>GMDN Code</b>	55985 – Prothrombin time (PT), IVD, control
<b>Classification</b>	General IVD
<b>Conformity Assessment Route</b>	The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) through Annex III (excluding Section 6) of 98/79/EC


is in conformity with the following UK Regulations and Directives as transposed into the national laws of the member states:

Directives and Regulations
SI 2002 No 618 (As Amended) Medical Devices Regulations 2002

This declaration is also supported by the following applied standards:

Standards/Common Specifications	
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Applications of Risk Management to Medical Devices

Full responsibility and compliance of the product is signed for and on the behalf of Manufacturer LumiraDx UK Limited:

<b>Name</b>	David Scott	<b>Position:</b>	Chief Technology Officer
<b>Signature</b>			<b>Date:</b>
			24 May 2022

With approval of this Declaration of Conformity, we hereby affix the UKCA Mark to the product.

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	<b>Document Number:</b>	S-RA-REP-00461

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