UKCA Declaration of Conformity for LumiraDx HbA1c and Quality Controls (S-RA-TEC-0024)

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Contents

UK Declaration of Conformity for LumiraDx HbA1c and Quality Controls (EN)

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

Legal Manufacturer:	LumiraDx UK Ltd.
Address:	Dumyat Business Park Alloa FK10 2PB United Kingdom

that the identified product to which this declaration relates,

Identification	
Product Name	LumiraDx HbA1c
Catalogue Number	L0060001nnxxx (where nn represents two digits corresponding to language variants, and where xxx represents three digits corresponding to number of units the catalogue number contains).
GMDN Code	66539, Glycated haemoglobin (HbA1c) IVD, kit, rapid microfluidic immunoassay, clinical.
Classification	General IVD
Conformity Assessment Route	The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) through Annex III (excluding Section 6) of 98/79/EC
Product Name	LumiraDx HbA1c Quality Controls
Catalogue Number	L0060801nnxxx (where nn represents two digits corresponding to language variants, and where xxx represents three digits corresponding to number of units the catalogue number contains).
GMDN Code	44435, Glycated haemoglobin (HbA1c) IVD, control
Classification	General IVD
Conformity Assessment Route	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:

Name	David Scott	Position:	Chief Technology Officer
Signature		Date:	
Original Declaration of Conformity signed (S-RA-REP-00456 Rev 1) by David Scott		24 May 2022	
DS		10 NOV 2022	

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