



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

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

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

Legal Manufacturer:	LumiraDx UK Ltd.
Address:	Dumyat Business Park Alloa FK10 2PB United Kingdom
EC Authorized Representative:	LumiraDx AB Västra Vägen 5A 169 61 Solna Sweden



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	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	Annex III (excluding Section 6) of 98/79/EC

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

Directives and Regulations
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

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-00455 Rev 1) by David Scott	24 May 2022		
			

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