



IVD Technical File Declaration of Conformity for LumiraDx NT-proBNP and Quality Controls (S-RA-TEC-0026)

Document Number:	S-RA-REP-00457	Revision:	1
Information Classification	Public		



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EC Declaration of Conformity for LumiraDx NT-proBNP 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 NT-proBNP
Catalogue numbers :	L0230001nnxxx (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	47352, B-type natriuretic protein/N-terminal pro b-type natriuretic peptide IVD, kit, fluorescent immunoassay
Classification	General IVD
Conformity Assessment Route	Annex III (excluding Section 6) of 98/79/EC
Product Name	LumiraDx NT-proBNP Quality Controls
Catalogue number	L0230801nnxxx (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	47354, B-type natriuretic protein/N-terminal pro b-type natriuretic peptide 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:		
	25 May 2022		

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