IVD Technical File Declaration of Conformity for LumiraDx SARS-CoV-2 & RSV and Quality Controls (S-RA-TEC-0022)

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Contents

EC Declaration of Conformity for LumiraDx SARS-CoV-2 & RSV 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
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 SARS-CoV-2 & RSV
Catalogue numbers :	L0210001nnxxx (where nn represents two digits corresponding to language variants, and where xxx represents three digits corresponding to number of units the catalogue number contains).
Catalogue numbers (with swabs):	L0210002nnxxx (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	66045, Multiple respiratory virus antigen IVD, kit, rapid fluorescent immunoassay
Classification	General IVD
Conformity Assessment Route	Annex III (excluding Section 6) of 98/79/EC
Product Name	LumiraDx SARS-CoV-2 & RSV Quality Controls
Catalogue number	L0210801nnxxx (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	48247, Multiple respiratory virus antigen 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:**	
		24-May-2022	

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