IVD Technical File Declaration of Conformity for LumiraDx SARS-CoV-2 & Flu A/B and Quality Controls (S-RA-TEC-0012)

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Contents

EC Declaration of Conformity for LumiraDx SARS-CoV-2 & Flu A/B (EN) and LumiraDx SARS-CoV-2 & Flu A/B 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 products to which this declaration relates,

Identification	
Product Name	LumiraDx SARS-CoV-2 & Flu A/B
Catalogue Numbers (without swabs)	L019000101012, L019000101024, L019000101048, L019000102012, L019000102024, L019000102048, L019000104012,L019000104024, L019000104048, L019000105012, L019000105024, L019000105048, L019000108012, L019000108024, L019000108048
Catalogue Numbers (with swabs)	L019000201012, L019000201024, L019000201048, L019000202012, L019000202024, L019000202048, L019000204012,L019000204024, L019000204048, L019000205012, L019000205024, L019000205048, L019000208012, L019000208024, L019000208048
GMDN Code	66045 - SARS-CoV-2/influenza A/B antigen IVD, kit, fluorescent immunoassay, rapid
Classification	General IVD
Conformity Assessment Route	Annex III (excluding Section 6) of 98/79/EC
Product Name	LumiraDx SARS-CoV-2 & Flu A/B Quality Controls
Catalogue Numbers	L019080101002, L019080102002
GMDN Code	65646 - SARS-CoV-2/influenza A/B 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:**	
Previously signed (S-RA-REP-00355 Rev 1) by David Scott under GMDN code for LumiraDx SARS-CoV-2 & Flu A/B test strips: 61885-Multiple respiratory pathogen antigen IVD, kit, fluorescent immunoassay		22 December 2021	
DSCott.		04 MARCH 2022	

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