

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

Document Number:	S-RA-REP-00355	Revision:	4
Information Classification		Public	



2 of 4

### **Contents**

EC Declaration of Conformity for LumiraDx SARS-Co\	'-2 & Flu A/B (EN) and LumiraDx SARS-CoV-2 8
Flu A/B Quality Controls (EN)	

Document Name: IVD Technical File Declaration of Conformity for LumiraDx SARS-CoV-2 & Flu A/B

and Quality Controls (S-RA-TEC-0012)

Document Number: S-RA-REP-00355 Revision: 4



## 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)	L0190001nnxxx (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)	L0190002nnxxx (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	48243 - Multiple respiratory virus antigen IVD, kit, fluorescent immunoassay.			
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	L0190801nnxxx (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			

3 of 4

Document Name: IVD Technical File Declaration of Conformity for LumiraDx SARS-CoV-2 & Flu A/B

and Quality Controls (S-RA-TEC-0012)

Document Number:

S-RA-REP-00355

Revision: 4



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- 00355 Rev 1) by David Scott		22 December 2021	
DScett.		10 Nov 2022	

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

Document Name:

4 of 4

IVD Technical File Declaration of Conformity for LumiraDx SARS-CoV-2 & Flu A/B

and Quality Controls (S-RA-TEC-0012)

Document Number:

S-RA-REP-00355

Revision: 4