IVD Technical File Declaration of Conformity for SARS-CoV-2 Ag Quality Controls (S-RA-TEC-0008)

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Contents

EC Declaration of Conformity
(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 5 A 169 61 Solna Sweden

that the identified product to which this declaration relates,

Identification	
Product Name	LumiraDx SARS-CoV-2 Ag Quality Controls
Catalogue Number	L016080101002
GMDN Code	64922 – SARS-CoV-2 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:**	
		**15th September 2020**	

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