

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

Document Number:	S-RA-REP-00130	Revision:	1
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## **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:

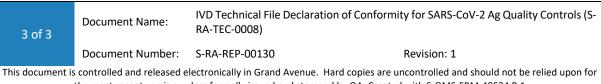
#### **Directives and Regulations**

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:	
DSAD.		15 <sup>th</sup> September 2020	

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



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