



## **IVD Technical File Declaration of Conformity for SARS-CoV-2 Ab Test Strips S-RA-TEC-0009**

Document Number:	S-RA-REP-00128	Revision:	1
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## Contents

Declaration of Conformity..... 3

## EC Declaration of Conformity (EN)

We, the legal manufacturer, as stated below hereby declares under our sole responsibility,

<b>Legal Manufacturer:</b>	LumiraDx UK Ltd
<b>Address:</b>	Dumyat Business Park Alloa FK10 2PB United Kingdom
<b>EC Authorized Representative:</b>	LumiraDx AB Västra Vägen 5A 169 61 Solna Sweden


that the identified product to which this declaration relates,

Identification	
<b>Product Name</b>	LumiraDx SARS-CoV-2 Ab Test Strips
<b>Catalogue Number</b>	L0170001nnxxx (where nn represents two digits corresponding to language variants, and where xxx represents three digits corresponding to number of units the catalogue number contains).
<b>GMDN Code</b>	64839 – SARS-CoV-2 immunoglobulin G(IgG)/IgM antibody IVD, kit, fluorescent immunoassay, rapid
<b>Classification</b>	General IVD
<b>Conformity Assessment Route</b>	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:

<b>Name</b>	David Scott	<b>Position:</b>	Chief Technology Officer
<b>Signature</b>			<b>Date:</b>
			18 <sup>th</sup> September 2020

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

3 of 3	Document Name: IVD Technical File Declaration of Conformity for SARS-CoV-2 Ab Test Strips S-RA-TEC-0009	Revision: 1
	Document Number: S-RA-REP-00128	