



IVD Technical File Declaration of Conformity for SARS-CoV-2 Ag Test Strips S-RA-TEC-0007

Document Number:	S-RA-REP-00127	Revision:	1
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EC Declaration of Conformity (EN)

We, the legal manufacturer, as stated below hereby 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

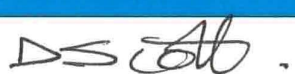
that the identified product to which this declaration relates,

Identification	
Product Name	LumiraDx SARS-CoV-2 Ag Test Strips
Catalogue Number	L0160001nnxxx (where 'nn' represents two digits corresponding to language variants, and where 'xxx' represents three digits corresponding to pack size).
GMDN Code	64829 – SARS-CoV-2 antigen IVD, kit, fluorescent immunoassay, rapid
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:
			26 AUGUST 2020

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

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