

UKCA Declaration of Conformity for LumiraDx SARS-CoV-2 Ag Ultra (S-RA-TEC-0021)

Document Number:	S-RA-REP-00435	Revision:	2
Information Classification		Public	



Contents

LIK Declaration of Conformity for LumiraDx SARS-CoV-2 Ag Ultra (EN)	3
TIK Declaration of Conformity for Luffillaby SANS-Cov-2 Ag Oldia (Liv)	

Document Name:

UKCA Declaration of Conformity for LumiraDx SARS-CoV-2 Ag Ultra (S-RA-TEC-

0021)

Document Number: S-RA-REP-00435

Revision: 2



UK Declaration of Conformity for LumiraDx SARS-CoV-2 Ag Ultra (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 product to which this declaration relates,

Identification (1997)		
Product Name	LumiraDx SARS-CoV-2 Ag Ultra	
Catalogue Numbers GMDN Code	L0160004nnxxx (where nn represents two digits corresponding to language variants, and where xxx represents three digits corresponding to number of units the catalogue number contains). 64829, SARS-CoV-2 antigen, IVD, kit, fluorescent immunoassay,	
	rapid	
Classification	General IVD	
Conformity Assessment Route	The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) through Annex III (excluding Section 6) of 98/79/EC	

is in conformity with the following UK Regulations and Directives as transposed into the national laws of the member states:

Directives and Regulations	Waster Fil
SI 2002 No 618 (As Amended) Medical Devices Regulations 2002	

UKCA Declaration of Conformity for LumiraDx SARS-CoV-2 Ag Ultra (S-RA-TEC-Document Name:

0021)

3 of 4

S-RA-REP-00435 Document Number: Revision: 2

This document is controlled and released electronically in Grand Avenue. Hard copies are uncontrolled and should not be relied upon for the most recent version unless formally issued and stamped by QA. Created with S-QMS-FRM-40641 R.1

Information Classification: Public



This declaration is also supported by the following applied standards:

Standards/Common Specifications		
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes	
EN ISO 14971:2019	Medical Devices – Applications of Risk Management to Medical Devices	

Full responsibility and compliance of the product is signed for and on the behalf of Manufacturer LumiraDx UK Limited:

Name	David Scott	Position:	Chief Technology Officer
Signature		Date:	
Original Declarat 00435 Rev 1) by [ion of Conformity signed (S-RA-REP- David Scott		19 May 2022
DSOB.		24 May 2022	

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

Document Name:

UKCA Declaration of Conformity for LumiraDx SARS-CoV-2 Ag Ultra (S-RA-TEC-

0021)

Document Number:

S-RA-REP-00435

Revision: 2