



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

Document Number: S-RA-REP-00434

Revision: 2

Information Classification

Public



Contents

EC Declaration of Conformity for LumiraDx SARS-CoV-2 Ag Ultra (EN)3

EC Declaration of Conformity for LumiraDx SARS-CoV-2 Ag Ultra (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 Ultra |
| Catalogue numbers | 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). |
| Catalogue numbers (with swabs) | L0160005nnxxx (where nn represents two digits corresponding to language variants, and where xxx represents three digits corresponding to number of units the catalogue number contains). |
| 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 |


| | |
|--------|---|
| 3 of 4 | Document Name: IVD Technical File Declaration of Conformity for LumiraDx SARS-CoV-2 Ag Ultra (S-RA-TEC-0021) |
| | Document Number: S-RA-REP-00434 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 SD-QMS-FRM-40524 R.1

Information Classification: Public



Signed for and on the behalf of Manufacturer LumiraDx UK Limited:

| | | | |
|---|--------------|------------------|--------------------------|
| Name | David Scott | Position: | Chief Technology Officer |
| Signature | Date: | | |
| Original Declaration of Conformity signed (S-RA-REP-00434 Rev 1) by David Scott | | | 19 May 2022 |
|  | | | 24-May-2022 |

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