



UKCA Declaration of Conformity for LumiraDx SARS-CoV-2 Ab Test Strips (S-RA-TEC-0009)

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| Document Number: | S-RA-REP-00468 | Revision: | 2 |
| Information Classification | Public | | |

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UK Declaration of Conformity for LumiraDx SARS-CoV-2 Ab Test Strips (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 |

that the identified product to which this declaration relates,

| Identification | |
|------------------------------------|--|
| Product Name | LumiraDx SARS-CoV-2 Ab Test Strips |
| Catalogue Numbers | 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). |
| GMDN Code | 66470, SARS-CoV-2 immunoglobulin G (IgG)/IgM antibody IVD, kit, rapid microfluidic immunoassay, clinical |
| 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 |
|--|
| SI 2002 No 618 (As Amended) Medical Devices Regulations 2002 |

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 |


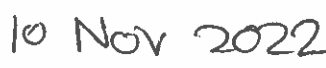
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| 3 of 4 | Document Name: UKCA Declaration of Conformity for LumiraDx SARS-CoV-2 Ab Test Strips (S-RA-TEC-0009) Document Number: S-RA-REP-00468 Revision: 2 |
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Information Classification: Public



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 Declaration of Conformity signed (S-RA-REP-00468 Rev 1) by David Scott | 25 May 2022 | | |
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With approval of this Declaration of Conformity, we hereby affix the UKCA Mark to the product.