LumiraDx

# EC Declaration of Conformity
(EN)

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

| | |
|---|---|
| **Legal Manufacturer:** | LumiraDx UK Ltd |
| **Address:** | Dumyat Business Park<br>Alloa FK10 2PB<br>United Kingdom |

**that the identified product to which this declaration relates,**

| **Identification** | |
|---|---|
| **Product Name** | LumiraDx Instrument |
| **Product Identification** | SPEC 30717 |
| **Catalogue Number** | L0010002nn001 (where nn represents two digits corresponding to language variants) |
| **GMDN Code** | 62540 – Coagulation Analyser IVD, Point-of-Care, Line-Powered |
| **Classification** | General IVD – as referred to by Article 9, §1 of 98/79/EC |
| **Conformity Assessment Route** | Annex III (excluding §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 |
| Directive 2011/65/EU of the European Parliament and of the Countil of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical or electronic equipment |
| Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC |

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

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|---|---|---|---|
| **Name** | Veronique Ameye | **Position:** | Director |
| **Signature** | | **Date:** | July 15 2020 |

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