IVD Technical File Declaration of Conformity for V5E Instrument S-RA-TEC-0004

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Contents

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 Alloa FK10 2PB United Kingdom
EC Authorized Representative:	LumiraDx AB Västra Vägen 5 A 169 61 Solna Sweden

that the identified product to which this declaration relates,

Identification	
Product Name	LumiraDx Instrument
Product Identification	SPEC 30874
Catalogue Number	L0010003nn001 (where 'nn' represents two digits corresponding to language variants)
GMDN Code	47057 – Portable fluorescent immunoassay analyser IVD battery-powered
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
Directive 2011/65/EU of the European Parliament and of the Council 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 radio equipment

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

Name	David Scott	**Position:**	Chief Technology Officer
Signature		**Date:**	
		**26 AUG 2020**	

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