IVD Technical File Declaration of Conformity for D-Dimer Test Strips

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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 5A 169 61 Solna Sweden

that the identified product to which this declaration relates,

Identification	
Product Name	LumiraDx D-Dimer Test Strips
Catalogue Number	L0050001nnxxx (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	61389 - D-Dimer IVD, kit, fluorescent immunoassay
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

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

Name	David Scott	**Position:**	Chief Technology Officer
Signature		**Date:**	
		**18th September 2020**	

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