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 Alloa FK10 2PB United Kingdom

that the identified product to which this declaration relates,

Identification	
Product Name	LumiraDx INR Test Strips
Catalogue Number	L003001nn012, L003001nn048 (where nn represents two digits corresponding to language variants)
GMDN Code	55983 – Prothrombin (PT), IVD, Kit, Clotting
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

Signed for and on the behalf of LumiraDx UK Limited:

Name	Veronique Ameye	**Position:**	Executive VP & Legal Counsel
Signature		**Date:**	
		July 15, 2020	

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

This document was originally signed on 10 November 2018. This version includes specific catalogue numbers of inclusive products.