IVD Technical File Declaration of Conformity for LumiraDx SARS-CoV-2 Ag Ultra Pool (S-RA-TEC-0028)

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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 SARS-CoV-2 Ag Ultra Pool
Catalogue numbers	L0160007nnxxx (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	64829, SARS-CoV-2 antigen, IVD, kit, fluorescent immunoassay, rapid
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:**	
Original Declaration of Conformity signed (S-RA-REP-00439 Rev 1) by David Scott		21 May 2022	
DScott.		24 May 2022	

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