IVD Technical File Declaration of Conformity for LumiraDx Multi Quality Control (S-RA-TEC-0017)

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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 Multi Quality Control
Catalogue Numbers	L020080101003 L020080102003
GMDN Code	47016 - A material which is used to verify the performance of an assay intended to be used for the qualitative and/ or quantitative detection of a combination of different types of cardiac markers in a clinical speciman. The cardiac markers may include B-type natriuretic protein, D-dimer, creatine kinase myocardial isoenzyme (CKMB), myoglobin, myeloperoxidase (MPO), fatty acid binding protein (FABP), glycogen phosphorylase isoenzyme BB (GPBB), troponin I and/or troponin T.
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:**	
		14th January 2022	

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