Declaration of Conformity

Product Identification

Product Name: xTAG® Cystic Fibrosis (CFTR) 39 kit v2

Manufacturer

Name: Luminex Molecular Diagnostics, Inc.

Address: 439 University Avenue
Toronto, ON, Canada
M5G 1Y8

Country: Canada

Representative: Bojana Ilic, Manager, Regulatory Affairs

Authorized European Representative within European Union (EU)

Name: DiaSorin Italia S.p.A.

Registered Address: DiaSorin Italia S.p.A.
Via Crescentino, snc
13040 Saluggia (VC)
Italy

EU Country: Italy

Notified Body

Name: Not applicable (Self-Declaration)

EU Country: Not Applicable

Means of Conformity

The undersigned declares that this product is designed, developed, and manufactured according to EN ISO 13485:2016, and fulfils the obligations imposed by "Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on *in vitro* diagnostic medical devices" in accordance with Annex I: Essential Requirements and Annex III: EC Declaration of Conformity (Article 6 is not applicable).

Approval Signature

CE

Bojana Ilic (Manager, Regulatory Affairs) Date

Description

The xTAG® Cystic Fibrosis (CFTR) 39 kit v2 is a genotyping test indicated in adults for detecting mutations in the CFTR gene and in newborns and children as an aid in the diagnosis of suspected cystic fibrosis.

Classification

General IVD

List of System Components

Description	Format	LMD Catalogue Number
Kit		
xTAG® Cystic Fibrosis (CFTR) 39 kit v2	96 tests/kit	I027C0232
Software		
xTAG® Cystic Fibrosis (CFTR) 39 kit v2 CD	CD	S027-0250

Applicable Standards

- EN ISO 13485:2016- Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- EN 13612:2002 – Performance evaluation of in vitro diagnostic medical devices
- BS EN 23640:2015 - In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
- BS EN ISO 14971:2019 Medical devices. Application of risk management to medical devices
- EN 980:2008 - Graphical symbols for use in the labeling of medical devices for use within the European Union (EU)
- ISO 18113-1:2011 In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 1: Terms, definitions and general requirements
- ISO 18113-2:2011 In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 2: In vitro diagnostic reagents for professional use
- ISO 17511:2003 - In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values assigned to calibrators and control materials
- ISO 15223-1:2016 – Medical Devices Symbols to be used with Medical Devices Labels, Labeling and information to be supplied
- CLSI Guidances as listed in The Essential Requirements Checklist - TRR-732-026-004
- Other ancillary standards indicated in the Technical File

Applicable Regulations

- EU In Vitro Diagnostic Directive (98/79/EC)
- USA FDA 21 CFR 820
- Canadian Medical Device Regulations
- Regulation 1272/2008 – Classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006