Declaration of Conformity

Product Identification

Product Name: xTAG® CYP2C19 Kit v3

Manufacturer

Name: Luminex Molecular Diagnostics, Inc.

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

Country: Canada

Representative: Bojana Ilic, Manager, Regulatory Affairs

Authorised 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 (Section 6 is not applicable).

Approval Signature

Electronically signed by: Bojana Ilic
Reason: By entering my electronic signature I acknowledge this to be the legally binding equivalent of my handwritten signature.
Date: Jun 29, 2023 15:36 EDT

Bojana Ilic (Manager, Regulatory Affairs)

06/29/2023
Date

CE

Description

xTAG® CYP2C19 Kit v3 is an *in vitro* device used to simultaneously detect and identify a panel of nucleotide variants found within the highly polymorphic CYP2C19 gene, located on chromosome 10q24, from genomic DNA extracted from EDTA or citrate anticoagulated whole blood samples. The xTAG® CYP2C19 Kit v3 is a qualitative genotyping assay which can be used as an aid to clinicians in determining therapeutic strategy for therapeutics that are metabolized by the CYP2C19 gene product, specifically, *1, *2, *3, *4, *5, *6, *7, *8, *9, *10 and *17. xTAG® CYP2C19 Kit v3 is not indicated for stand-alone diagnostic purposes.

Classification

General IVD

List of System Components

Description	Format	Catalogue Number
Kit		
xTAG® CYP2C19 Kit v3	48	I046B0428
Software		
TDAS CYP2C19	CD	S046-0276

Applicable Standards

- EN ISO 13485:2016- Quality Management Systems: Medical Devices-System
- EN 13612:2002 - Performance evaluation of in vitro diagnostic medical devices
- EN 23640:2015 –Evaluation of stability of In Vitro Diagnostic Reagents
- EN ISO 14971:2019 - Medical Devices: Application of Risk Management to Medical Devices
- 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 18113-3:2011 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use
- 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-732-047-002

Applicable Regulations

- EU In Vitro Diagnostic Directive (98/79/EC)
- USA FDA 21 CFR 820
- Canadian Medical Device Regulations
- Directive 88/379/EEC
- Directive 1999/45/EC
- Directive 67/548/EEC