eurofins | LifeCodexx

valid from: 2020-01-30

EC – Declaration of Conformity

for the In Vitro Diagnostic Medical Device mentioned below:

Product Name	**PrenaTest® dmap**
Version	**2.0**
Intended Use	**PrenaTest® dmap** is a Software for prenatal determination of the risk of fetal microdeletion 22q11.2 (DiGeorge syndrome) based on data generated by the CE-marked IVD product "VeriSeq™ NIPT Solution".
EDMA Code	27 02 - Data Management Software/Consumables
Classification	Determination of the risk of fetal microdeletion 22q11.2: In Vitro Diagnostic Medical Device other than those covered by Annex II 98/79/EC or for performance evaluation
Manufacturer	Eurofins LifeCodexx GmbH
Manufacturing Site	Line-Eid-Str. 3 78467 Konstanz Germany
	This declaration of conformity is issued under the sole responsibility of the manufacturer.
Conformity Assessment Procedure	The manufacturer declares to fulfill the obligations imposed by Annex III section 2 to 5: a. Availability of the technical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive. b. The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).

c. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

All essential requirements (Annex I) of the IVD Directive 98/79/EC are fulfilled. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.

The manufacturer has a quality management system based on ISO 13485:2016.

This declaration of conformity is valid for 10 years or until product changes.

Konstanz, January 30, 2020

i.A.

Signature Dr. Carmen Fehr (QMR)

ppa.

Signature Andrea Stephinger (Prokura)

i.V.

Signature Dr. Stephan Busche (Safety Officer for Medical Devices)