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valid from: 2019-12-10

EC – Declaration of Conformity

for the In Vitro Diagnostic Medical Device mentioned below:

Product Name	**PrenaTest® DAP.plus**
Version	**7.1**
Intended Use	**PrenaTest® DAP.plus** is a software for prenatal determination of the risk of fetal trisomy 13, 18 and 21 as well as gonosomal aneuploidies and microdeletions using maternal blood and the latest sequencing and PCR technologies.
EDMA Code	27 02 - Data Management Software/Consumables
Classification	Determination of the risk of fetal trisomy 21: In Vitro Diagnostic Medical Device, List B according to Annex II 98/79/EC All other determinations as outlined above: In Vitro Diagnostic Medical Device not listed in Annex II 98/79/EC (valid for all determinations except those with regards to trisomy 21)
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	Determination of the risk of fetal trisomy 21: We hereby declare that the above mentioned device has been manufactured according to Annex IV of the Directive 98/79/EC, excluding Sections 4 and 6 and complies with the German Act on Medical Devices (Medizinproduktegesetz) and the Directive 98/79/EC as of 27 October 1998 on In Vitro Diagnostic Medical Devices and the respective harmonized standards.

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	All other determinations as outlined above: We hereby declare that the above mentioned device has been manufactured according to Annex I of the Directive 98/79/EC and complies with the German Act on Medical Devices (Medizinproduktegesetz) and the Directive 98/79/EC as of 27 October 1998 on In Vitro Diagnostic Medical Devices and the respective harmonized standards.
Notified Body	TÜV Rheinland LGA Products GmbH (Notified Body Nr.: 0197) Tillystr. 2 90431 Nürnberg Germany
EC Certificate according to Directive 98/79/EC Annex IV, excluding Sections 4 and 6	Reg. Nr.: HL 60141883 0001 (valid only for determination with regards to trisomy 21)

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

Konstanz, 05 Dec. 2019

Signature Dr. Carmen Fehr (QMR)

Signature Andrea Stephinger (ppa.)