TÜVRheinland®

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60119430 0001

Report No.: 21178021 014

Manufacturer:
LifeCodexx AG
Line-Eid-Str. 3
78467 Konstanz
Deutschland

Products:
IVD software for prenatal diagnostics
- PrenaTest DAP.plus
The conformity assessment of the Notified Body is limited to aspects associated with the risk evaluation for trisomy 21.

Replaces Certificate, Registration No.: HL 60113436 0001

Expiry Date: 2022-06-21

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2017-06-22

Date: 2017-05-11

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.