



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 60113436 0001

Report No.: 21178021 012

**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 60091764 0001

**Expiry Date:** 2017-06-21

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:** 2016-08-26

**Date:** 2016-08-26



Notified Body

Dipl.-Ing. C. Wiora

**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.