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 60150067 0001

Report No.: 16805650 008

Manufacturer:

RUNBIO BIOTECH CO., LTD.
Rongsheng Technological Zone,
Univ. Road
SHANTOU City
515063 Guangdong
P.R. China

Products:

- Onestep Pregnancy Urine Tests for Self-testing
- Onestep Ovulation Urine Tests for Self-testing
- Onestep FSH Urine Tests for self-testing
- Male Fertility Sperm Tests for Self-testing

Replaces Approval, Registration No.: HL 60146350 0001

Expiry Date: 2024-05-26

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: 2020-06-29

Date: 2020-06-29

Notified Body
TÜV Rheinland LGA Products GmbH
Jing Zhang

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.