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 60149972 0001

Report No.: 15067822 020

Manufacturer:

Hangzhou Sejoy Electronics &
Instruments Co., Ltd.
Area C, Building 2, No.365, Wuzhou Road
Yuhang Economic Development Zone
Hangzhou City
311100 Zhejiang
P.R. China

Products:

Blood Glucose Monitoring Systems:
- Blood Glucose Meters
- Blood Glucose Test Strips
- Blood Glucose Test Controls

Replaces Approval, Registration No.: HL 60137407 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: 2020-09-08

Date: 2020-09-08

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Herbert Zhong

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.

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