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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 060250 0017 Rev. 01

Manufacturer: **Changsha Sinocare Inc.**
No. 265 Guyuan Road, Hi-Tech Zone
410205 Changsha
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): In Vitro diagnostic devices for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.: SH1849813

Valid from: 2019-01-09
Valid until: 2022-02-26

Date, 2019-01-09

Stefan Preiß

Digitally signed by Granaci Boris
Date: 2022.02.02 09:40:11 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 060250 0017 Rev. 01

Model(s):

Blood Glucose Monitoring System (SXT series, Safe-Accu series, Gold-Accu series, Safe AQ series, Gold AQ series),include Blood Glucose Meter, Blood Glucose Test Strip,Blood Glucose Control Solution

Blood Glucose Monitoring System (Dnurse series), include Blood Glucose Meter, Blood Glucose Test Strip, Control Solution and APP

Blood Glucose and Uric Acid Monitoring System (EA series, Safe AQ series), include Blood Glucose and Uric Acid Meter, Blood Glucose Test Strip, Uric Acid Test Strip, Control Solution

Blood Glucose and Ketone Monitoring System (Safe AQ series), include Blood Glucose and Ketone Meter, Blood Glucose Test Strip, Ketone Test Strip, Control Solution

Microalbuminuria Test Strip

Facility(ies):

Changsha Sinocare Inc.
No. 265 Guyuan Road, Hi-Tech Zone, 410205 Changsha,
PEOPLE'S REPUBLIC OF CHINA

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