



China

TUV SUD China Shanghai Branch - No.151 Hengtong Road, Shanghai  
200070 Shanghai, P.R. China

Date: 2021-12-29

## To Whom It May Concern

This letter is to confirm that the client

**Changsha Sinocare Inc.**

Located at

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

Is the legal manufacturer for Directive 98/79/EC (IVDD) CE certificate no. V1 060250 0017 Rev 001. TÜV SÜD has done on-site audit (add new product) combine CE certificate extension in 2021-09-07 – 2021-09-09 with scope

**Blood Glucose Monitoring System (SXT series, Safe-Accu series, Gold-Accu series, Safe AQ series, Safe AQ pro series, Safe AQ max 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**



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**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 Uric Acid Monitoring System (model SPUG), include Blood Glucose and Uric Acid Meter, Blood Glucose Test Strip, Uric Acid Test Strip, Control Solution and APP**

**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**

Audit file (project number SH2149802) has already been submitted to the certification body. Auditor team recommends to issue IVDD CE certificate to this client. The certification decision process is ongoing by certification body now.

**Medical-Health-Service**

A handwritten signature in black ink, appearing to read 'Weng', written over a horizontal line.

Mr. Chenchuan Weng

Project handler

