Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2139300-1

Organization: Safecare Biotech (Hangzhou) Co., Ltd.
Building 2/203, No.18 Haishu Rd.,
Cangqian Sub-district, Yuhang District,
Hangzhou
311121 Zhejiang
P.R. China

Scope: Design and Development, Manufacture and Distribution of in vitro diagnostic medical devices(reagents) used in the detection of the Fertility testing, Drug of Abuse, Cardiac Markers, Infectious Diseases including (home use, near patient/point of care) in vitro diagnostic devices; Distribution of in vitro diagnostic medical devices (instruments) used in the detection of the Fertility testing, Drug of Abuse, Cardiac Markers, Infectious Diseases including(home use, near patient/point of care) in vitro diagnostic devices

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244427482-200
Effective date: 2022-11-03
Expiry date: 2023-06-06
Issue date: 2022-11-03

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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Cangqian Sub-district, Yuhang District,
Hangzhou
311121 Zhejiang
P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Zhejiang AISAI Technology Co.,Ltd South Baixi Road, West Changxing Avenue, Development Zone, Changxing Huzhou, 311121 Zhejiang P.R. China	Manufacture of in vitro diagnostic medical devices(reagents) used in the detection of the Fertility testing, Drug of Abuse, Cardiac Markers, Infectious Diseases including(home use, near patient/point of care) in vitro diagnostic devices

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02