

Certificate

Quality Management System EN ISO 13485:2016

Registration No.	SX 2139300-1
Certificate Holder	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.	244496696-200
Effective date	2023-06-07
Expiry date	2026-06-06
Issue date	2023-06-06
Replaces certificate SX 2139300-1 issued 2022-11-03	



Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Hangzhou
311121 Zhejiang
P.R. China

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Safecare Biotech (Hangzhou) Co., Ltd. Building 2/203, No.18 Haishu Rd., Cangqian Sub-district, Yuhang District, Hangzhou 311121 Zhejiang P.R. China	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
/02	c/o Zhejiang Aisai Technology Co.,Ltd No. 689, Changxing Avenue, Taihu Street, Changxing County, Huzhou City, 313100 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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