

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Huaian Helen Medical Instrument
Co., Ltd.**
Group 3, Zhengtai Village
Matou Town, Huaiyin District
Huaian
223345 Jiangsu
China

has established and applies a quality management system for medical devices
for the following scope:

**Manufacture and Distribution of Sterile Blood Lancets,
Disposable Surgical Blades & Scalpels with Plastic Handle**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-12-21
Certificate Registration No.: SX 60134640 0001
An audit was performed. Report No.: 15096311 002
This Certificate is valid until: 2021-09-28

Certification Body



Date 2018-12-21



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