

Certificate

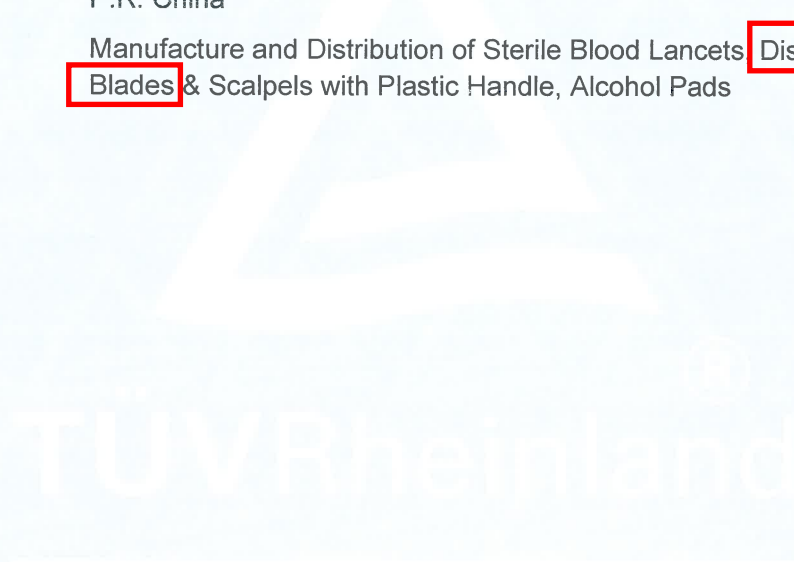


Quality Management System
EN ISO 13485:2016

Registration No.: SX 2113165-1

Organization: Huaian Helen Medical Instrument
Co., Ltd.
Group 3, Zhengtai Village,
Matou Town, Huaiyin District,
Huaian
223345 Jiangsu
P.R. China

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



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.: 244335565-200
Effective date: 2021-09-29
Expiry date: 2024-09-28
Issue date: 2021-08-31



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