



**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60134639 0001

**Report No.:** 15096311 002

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

**Products:**  
- Sterile Blood Lancets  
- Disposable Surgical Blades & Scalpels with Plastic Handle

**Expiry Date:** 2023-09-28

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2018-12-21

**Date:** 2018-12-21



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



# 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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