



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

Registration No.: DD 60136001 0001

Report No.: 15065241 009

Manufacturer: Huaian Angel Medical Instruments
Co., Ltd.
19 East Zhuhai Road
Huaian
223001 Jiangsu
China

Products: Medical Devices
(see attachment for products included) 
Replaces Approval, Registration No.: DD 60101257 0001

Expiry Date: 2024-01-26

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: 2019-01-27

Date: 2019-01-17

Notified Body



Herbert Zhong

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60136001 0001
Report No.: 15065241 009

Manufacturer: Huaian Angel Medical Instruments
Co., Ltd.
19 East Zhuhai Road
Huaian
223001 Jiangsu
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Products:

- Disposable Suture Needles
- Disposable Surgical Blades & Scalpels with Plastic Handle
- Sterile Blood Lancets
- Surgical Instruments Kits

For the following medical devices the scope covers only
the aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Sterile Urinary Drainage Bags
- Disposable Umbilical Cord-Clamps

Date: 2019-01-17

Notified Body



Surgical Blades



- Material:Carbon,stainless
- Size:10#.11#,12#,15#,20#,21#,22#,23#,24#
- Package:100 pcs/box 5000 pcs/carton
- Feature:automatic grinding keep sharpness, Tungsten steel mold
- ensure stable dimension
- Sterilization:Gamma Irradiation

REF NO	<u>0710</u>	<u>0711</u>	<u>0712</u>	<u>0715</u>	<u>0720</u>	<u>0721</u>	<u>0722</u>	<u>0723</u>	<u>0724</u>	carbon
	0810	0811	0812	0815	0820	0821	0822	0823	0824	stainless
SIZE	10#	11#	12#	15#	20#	21#	22#	23#	24#	