

**EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ**

Name und Adresse des Herstellers: / Huaian Angel Medical Instruments Co., Ltd.
Name and address of the manufacturer: / 19 East Zhuhai Road, Huaian, Jiangsu 223001, P.R.China
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:
EC Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / Disposable Surgical Blades & Scalpe with Plastic Handle –
the medical device: / UMDNS Code: 15-558
le dispositif médical: /
il dispositivo medico:

der Klasse: / of class: / Class IIa
de la classe: / di classe:

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“.

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Directive 93/42/EEC Annex V
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Registrier-Nr.: / DD 60136001 0001
Registration No.: / Issue date: 2019-01-17
N° d'enregistrement: / Expire date: 2024-01-26
Numero di registrazione:

Benannte Stelle: / TÜV Rheinland LGA Products GmbH
Notified Body: / Tillystraße 2
Organisme notifié: / 90431 Nürnberg
Organismo notificato: / Deutschland
CE 0197

Huaian, 2021-8-23

Mr Cao, General Manager

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione



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)

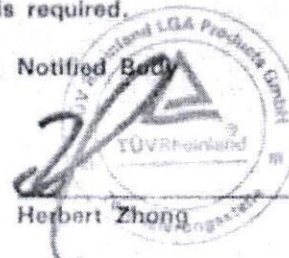
Replaces Approval, Registration No.: DD 60101257 0001

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



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.



Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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
China

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

Herbert Zhong

