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

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**Huaian Angel Medical Instruments Co., Ltd.** **19 East Zhuhai Road, Huaian, Jiangsu 223001, P.R.China**
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: / the medical device: / le dispositif médical: / il dispositivo medico:	**Disposable Surgical Blades & Scalpe with Plastic Handle – UMDNS Code: 15-558**
der Klasse: / of class: / de la classe: / di classe:	**Class IIa** 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: / Conformity assessment procedure: / Procédure d'évaluation de la conformité: / Procedura di valutazione della conformità:	**Directive 93/42/EEC Annex V**
Registrier-Nr.: / Registration No.: / N°d'enregistrement: / Numero di registrazione:	**DD 60136001 0001** **Issue date: 2019-01-17** **Expire date: 2024-01-26**
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Huaian, 2021-8-23

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

Mr Cao, General Manager

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

TÜVRheinland

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.

TÜVRheinland

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

Digitally signed by Chițanu Ion
Date: 2023.06.27 08:55:48 EEST
Reason: MoldSign Signature
Location: Moldova

Notified Body

Date: 2019-01-17

Herbert Zhong