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
Confirmation letter:	CL 043616 0028 Rev.00
Issue date:	2023-12-05
End date of extended validity:	2028-12-31
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Huaian, 2023-12-23

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

Mr Cao, General Manager

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

TÜV Rheinland®

TÜV Rheinland LGA Products GmbH

Date：2023-12-05

Huaian Angel Medical
Instruments Co., Ltd.
No.19 East Zhuhai Road,Huaian Jiangsu
P.R. China

TÜV Rheinland LGA Products GmbH
Confirmation Letter
CL 043616 0028 Rev. 00

Reference: 713305784

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV Rheinland LGA Products GmbH, designated under MDR and identified by the number 0197 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000014574

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV Rheinland LGA Products GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or

- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3a) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

26 May 2026 for Class III custom-made implantable devices

31 December 2027 for Class III devices and Class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

On behalf of the Notified Body TÜV Rheinland LGA Products GmbH

TÜV Rheinland LGA Products GmbH
Medical and Health Services

Jia Zhu

<Mr. Jia Zhu>
Conformity Assessment Responsible (CARE)

TÜV Rheinland LGA Products GmbH
Medical and Health Services

Mira Fischer
Application Reviewer

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Table 1: Devices covered by this letter and for which TÜV Rheinland LGA Products GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	Device name or Basic UDI-DI (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 Disposable Suture Needles (Basic UDI -DI: 6942194099924 9Y)	☐ Class III ☐ Class IIb implantable ☐ Class IIb implantable devices limited to exempted devices according to Article 52 MDR ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/Ass	☒ Certification as follows: Certificate #DD601360010001 Rev.01; NB# 0197
Device 2 Disposable Surgical Blades &Scalpels with Plastic Handle (Basic UDI -DI: 6942194099917A3)	☐ Class III ☐ Class IIb implantable ☐ Class IIb implantable devices limited to exempted devices according to Article 52 MDR ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #DD601360010001 Rev.01; NB# 0197
Device 3 Sterile Blood Lancets (Basic UDI -DI: 9421940999009J)	☐ Class III ☐ Class IIb implantable ☐ Class IIb implantable devices limited to exempted devices according to Article 52 MDR ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #DD601360010001 Rev.01; NB# 0197
Device 4 Surgical Instruments Kits (Basic UDI -DI: 6942194099894AG)	☐ Class III ☐ Class IIb implantable ☐ Class IIb implantable devices limited to exempted devices according to Article 52 MDR ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #DD601360010001 Rev.01; NB# 0197

Device name or Basic UDI-DI (under MDR application)	Device name or Basic UDI-DI (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 5 Sterile Urinary Drainage Bags (Basic UDI -DI: 6942194099887AK)	☐ Class III ☐ Class IIb implantable ☐ Class IIb implantable devices limited to exempted devices according to Article 52 MDR ☐ Class IIa ☐ Class I devices in sterile condition ☒ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #DD601360010001 Rev.01; NB# 0197
Device 6 Disposable Umbilical Cord-Clamps (Basic UDI -DI: 6942194099870A2)	☐ Class III ☐ Class IIb implantable ☐ Class IIb implantable devices limited to exempted devices according to Article 52 MDR ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #DD601360010001 Rev.01; NB# 0197

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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

TÜVRheinland LGA Products GmbH

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.

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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

Notified Body

Date: 2019-01-17

Herbert Zhong