EC Certificate

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

Registration No.: DD 60137254 0001

Report No.: 15068147 008

Manufacturer:
Changzhou Yuekang
Medical Appliance Co., Ltd.
Jiaoxi Town, Wujin County
213116 Changzhou, Jiangsu
China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60109881 0001

Expiry Date: 2024-03-12

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: 2019-03-13

Date: 2019-03-13

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle
S. Liu

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.

Digitally signed by Potînga Stela
Date: 2023.03.23 11:52:04 EET
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Location: Moldova

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60137254 0001
Report No.: 15068147 008

Manufacturer:
Changzhou Yuekang
Medical Appliance Co., Ltd.
Jiaoxi Town, Wujin County
213116 Changzhou, Jiangsu
China

Products:

Disposable Syringes, Disposable Infusion Sets, Disposable Blood Transfusion Sets, Disposable Intravenous Needles, Disposable Hypodermic Needles, Extension Tubes for Single Use, Urine Bags for Single Use, Vaginal Speculums for Single Use, Nelaton Catheters, Suction Catheters, Feeding Tubes, Stomach Tubes, Rectal Tubes, Disposable I.D. Bracelets, Paediatric Urine Collectors, Wound Plasters, Medical Tapes, Medical Dressings, Disposable Insulin Syringes, Disposable Tourniquets

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
III
Zertifizierungsstelle

Notified Body

Date: 2019-03-13

S. Liu

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:

Changzhou Yuekang Medical Appliance Co., Ltd.

Jiaoxi Town, Wujin County, Changzhou, Jiangsu 213116, China

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:

Syringe 50ML
UMDNS-CODE: 13217

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

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 60137254 0001

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Changzhou,CN 20th, Dec, 2021
Ort, Datum / Place, date /
Lieu, date / Luogo, data

Lu Qiao Qin, Director
Name und Funktion / Name and function /
Nom et fonction / Nome e funzione