



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

Registration No.: DD 60117375 0001

Report No.: 15096132 001

Manufacturer: Jiangsu Ostup Medical Products
Co., Ltd.
1st Floor, B7
Kechuang Road No. 9, Zhongshan
Technology Park, Luhe Zone
Nanjing
211500 Jiangsu
China

Products: Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Disposable Urine Bags

Expiry Date: 2022-04-12

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: 2017-05-24

Date: 2017-05-24

Notified Body

X. Ren

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.



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: / **Jiangsu Ostup Medical Products Co., Ltd.**
Nom et adresse du fabricant: / **B7, Kechuang Road No.9, Zhongshan Technology Park, Luhe**
Nome e indirizzo del fabbricante: **District, Nanjing, 211500, 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: / **Ostomy bags**

the medical device: /
le dispositif médical: /
il dispositivo medico:

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

I

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 IX

Registrier-Nr.: /
Registration No.: /
N° d'enregistrement: /
Numero di registrazione:

SX 60117376 0001

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

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

Nanjing, 17th March, 2017
Ort, Datum / Place, date /
Lieu, date / Luogo, data

江苏汇锦然医疗器械有限公司
Name und Funktion / Name and function /
Nom et fonction / Nome e funzione / **Jiangsu Ostup Medical Products Co., Ltd.**





Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Jiangsu Ostup Medical Products
Co., Ltd.**
1st Floor, B7
Kechuang Road No. 9, Zhongshan
Technology Park, Luhe Zone
Nanjing
211500 Jiangsu
China

has established and applies a quality management system for medical devices
for the following scope:

**Manufacture and Distribution of Disposable Urine Bags,
Ostomy Bags and Accessories, Hydrocolloid Dressings**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**

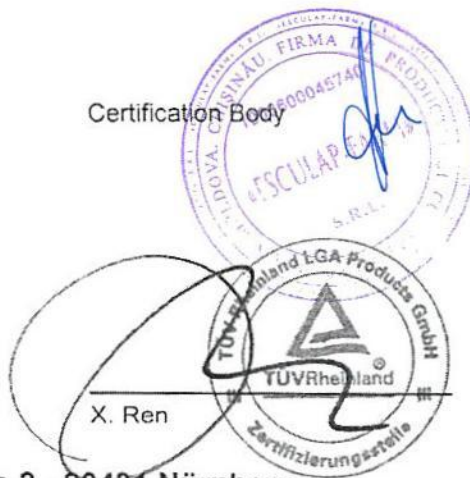
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-05-24
Certificate Registration No.: SX 60117376 0001
An audit was performed. Report No.: 15096132 001
This Certificate is valid until: 2019-02-28



Date 2017-05-24

Certification Body



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