TÜVRheinland®

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.

HJR/CE01-03 A/0

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:

Jiangsu Ostup Medical Products Co., Ltd.
B7,Kechuang Road No.9,Zhongshan Technology Park,Luhe 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

江苏汇鼎公医疗器械有限公司
Jiangsu Ostup Medical Products Co., Ltd.

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

TÜVRheinland®

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

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2017-05-24

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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