

APPROVAL
EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60023940 0001

Report No.: 15030375 001

Manufacturer: Wujiang City Cloud &
Dragon Medical Device Co., Ltd.
148 Yucai Road
Beishe Town, Wujiang City

Jiangsu Province, 215214
China

Scope: Manufacture of Disposable Medical Devices

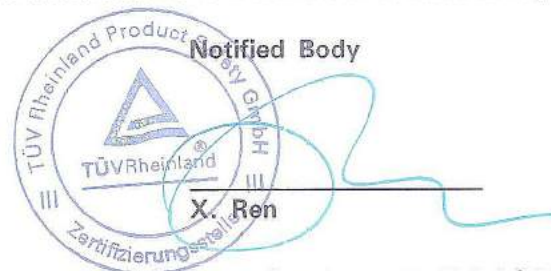
Products: see attachment

Replaces Approval, Registration No.: DD 60007186 0001

Date of Expiry: 19.02.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 20.02.2009



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with.



TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: DD 60023940 0001
Report No.: 15030375 001

Manufacturer: **Wujiang City Cloud &
Dragon Medical Device Co., Ltd.**
148 Yucai Road
Beishe Town, Wujiang City

Jiangsu Province, 215214
China

Scope:

Products:

- Disposable Blood Lancets
- Disposable Acupuncture Needles
- Disposable Dermal Needles
- Disposable Press Needles
- Disposable Tattoo Needles
- Disposable Ear Needles
- Disposable Intradermal Embedding Needles
- Dermal Rollings
- Disposable Tattoo Needles with Tubes

Cologne, 20.02.2009



Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization
**Wujiang City Cloud &
Dragon Medical Device Co., Ltd.**
148 Yucai Road
Beishe Town, Wujiang City
Jiangsu Province, 215214
China

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

**Manufacture and Distribution of Disposable
Medical Devices**
Products: see attachment

Proof has been furnished that the requirements specified in

EN ISO 9001:2000

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

Certificate Registration No.: SY 60023941 0001

An audit was performed. Report No.: 15030375 001

This Certificate is valid until: 14.11.2010

Certification Body

Cologne, 20.02.2009



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln

Tel.: (+49/221) 806 - 1371 Fax: (+49/221) 806 - 3935 e-mail:cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Doc. 1/1, Rev. 0

Attachment to
Registration No.: SY 60023941 0001
Report No.: 15030375 001

Organization: Wujiang City Cloud &
Dragon Medical Device Co., Ltd.
148 Yucai Road
Beishe Town, Wujiang City

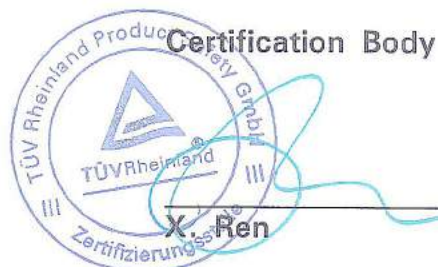
Jiangsu Province, 215214
China

Scope:

Products:

- Disposable Blood Lancets
- Disposable Acupuncture Needles
- Disposable Dermal Needles
- Disposable Press Needles
- Disposable Tattoo Needles
- Disposable Ear Needles
- Disposable Intradermal Embedding Needles
- Dermal Rollings
- Disposable Tattoo Needles with Tubes

Cologne, 20.02.2009



TÜV Rheinland / CCIC (Qingdao)

6F, No.2 Bldg., No.175 Zhuzhou Rd., Qingdao 266101, P.R. China

C E R T I F I C A T E

for a

Quality Management System

according to

EN ISO 13485:2003+AC:2007

TÜV Rheinland / CCIC (Qingdao) hereby certifies that the

Manufacturer: Wujiang City Cloud & Dragon
Medical Device Co., Ltd.
148 Yucai Road, Beishe Town
Wujiang City, Jiangsu Province 215214
P.R. China

has established and maintains a quality management system. Conformance with the requirements of the standards has been audited.

The organization is subject to a yearly surveillance audit.

Registration No.: SY 50147909 0001

Report No.: 15030375 001

Date of expiry: 19.02.2014

Scope: refer to Attachment

Qingdao, 20.02.2009



TÜV Rheinland / CCIC (Qingdao)
6F, No.2 Bldg., No.175 Zhuzhou Rd., Qingdao
266101, P.R. China

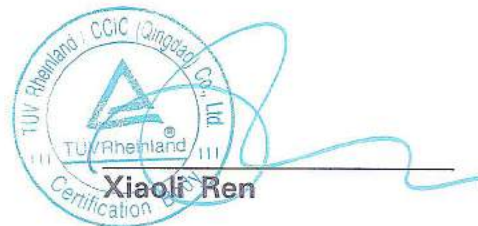
Attachment to

Registration No.: SY 50147909 0001
Report No.: 15030375 001

Manufacturer: Wujiang City Cloud & Dragon
Medical Device Co., Ltd.
148 Yucai Road, Beishe Town
Wujiang City, Jiangsu Province 215214
P.R. China

Scope: Manufacture and Distribution of Disposable Blood Lancets,
Disposable Acupuncture Needles, Disposable Dermal Needles,
Disposable Press Needles, Disposable Tattoo Needles,
Disposable Ear Needles, Disposable Intradermal Embedding
Needles, Dermal Rollings, Disposable Tattoo Needles
with Tubes

Qingdao, 20.02.2009



Certificate



TUV Rheinland of North America, Inc., a CMDCAS
recognized registrar, certifies that

**Wujiang City Cloud &
Dragon Medical Device Co., Ltd.**
148 Yucai Road
Beishe Town, Wujiang City
Jiangsu Province, 215214
China

has established and maintained a
Quality Management System
according to
ISO 13485:2003

Audit Report No.: 30893667 001
Certificate Registration No.: 74 500 3622
Expiry Date: February 19, 2012

for the Manufacture and Distribution of

Blood Lancets, Disposable Acupuncture Needles, Disposable
Dermal Needles, Disposable Press Needles, Disposable
Tattoo Needles, Disposable Ear Needles, Disposable
Intradermal Embedding Needles, Dermal Rollings, Disposable
Tattoo Needles with Tubes




Certification Officer: X. Ren

TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: February 20, 2009