

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

Registration No.: DD 60042214 0001

Report No.: 15045885 001

Manufacturer: Nubenco (Shanghai) Company Ltd.
Rm 6302, Building 6, No. 399
Cai Lun Road, Pudong District
201203 Shanghai
China

Scope: Manufacture of Medical Devices
(see attachment for products included)
Replaces Approval, Registration No.: DD 60025852 0001

Date of Expiry: 11.12.2016

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.

Date 12.12.2011



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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. CE

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Registration No.:** DD 60042214 0001
Report No.: 15045885 001

Manufacturer: Nubenco (Shanghai) Company Ltd.
Rm 6302, Building 6, No. 399
Cai Lun Road, Pudong District
201203 Shanghai
China

Scope:

Products:

- Sterile Syringes for Single Use
- Sterile Infusion Sets for Single Use
- Sterile Infusion Sets with Burette
- Sterile Blood Transfusion Sets for Single Use
- Sterile Hypodermic Needles
- Scalp Vein Sets for Single Use
- Dental Needles
- I. V. Catheters
- Fistula Needles
- Lancets
- Sterile Suction Catheters
- Sterile Feeding Tubes
- Sterile Nelaton Catheters
- Disposable Surgical Blades
- Sterile Scalpel with Plastic Handle
- Surgical Gloves
- Wound Drainage Systems
- Nebulizers
- Stopcocks
- Extension Tubes
- Oxygen Masks

Date 12.12.2011

Certification Body



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: DD 60042214 0001
Report No.: 15045885 001

Manufacturer: Nubenco (Shanghai) Company Ltd.
Rm 6302, Building 6, No. 399
Cai Lun Road, Pudong District
201203 Shanghai
China

Scope:

Products:

- Nasal Oxygen Cannula
- Laryngeal Mask Devices
- Multi-vent Masks
- Tracheal Tubes
- Oropharyngeal Airways
- Endobronchial Blocker Tubes
- Lap Sponges
- Sterile Gauze Swabs with X-ray detectable
- Sterile Gauze Balls with X-ray detectable

Aspects of manufacture concerned with securing and maintaining sterile conditions.

- Sterile Stomach Tubes
- Sterile Rectal Tubes
- Urine Bags
- Sterile Non-woven Swabs
- Sterile Gauze Swabs
- Adhesive Wound Dressings
- Transparent Island Dressings
- Transparent Semi-permeable Dressings
- Surgical Films
- Umbilical Clamps

Certification Body

Date 12.12.2011

X. Ren

