ii.

14



EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in class Lin sterile conditions, sterilised systems or procedure packs) No. G2S 16 01 73283 028

Manufacturer:	Ningbo Greetmed Medical Instruments Co., Ltd. 18F-3. No.1 Building Wante Business Centre, Hi-Tech Zone 315042 Ningbo PEOPLE'S REPUBLIC OF CHINA	
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg GERMANY	
Product Category(ies):	For detailed information please see attachment	
The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned		

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

SH16299EXT01

Valid from: Valid until: 2016-04-18 2021-04-17



Date, 2016-04-15

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no 0123 Page 1 of 3

TÜV SÜD Product Service GmbH + Zertifizierstelle + Ridlerstraße 65 + 80339 München + Germany

ͲͲϒ[®]

Scanned by CamScanner



EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 16 01 73283 028

Facility(ies):

Ningbo Greetmed Medical Instruments Co., Ltd. 18F-3, No.1 Building, Wante Business Centre, Hi-Tech Zone, 315042 Ningbo, PEOPLE'S REPUBLIC OF CHINA

Scanned by CamScanner

Page 2 of 3

Attachment for Certificate No G2S.16.01.73283.028



Supplement 001 dated 2016-04-15

For the product(s)/product category (ies):

Non-woven Swab, Gauze Swab, Elastic Bandage, Urine Bag, Umbilical Cord Clamp, First-Aid-Kit, Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Rectal Tube, Vaginal Speculum, Oropharyngeal Airway, Surgical Gowns, Surgical Brush, Absorbent Cotton Balls, Eye Pad, Dressing Kits, External Male Catheter, Gynecological Sets, Cervical Brushes, Nasal Speculas, Irrigation Syringes, Alcohol Swabs, Disposable Colostomy Bags, Nasopharyngeal Airway, Wooden Tongue Depressors, Male/Female Swab, Gauze Roll, Gauze Bandage, Isolation Gowns, Non-woven Face Masks, Sterile Urine Container, Sterile Examination Gloves, Surgical Drapes, Cotton Tipped Applicators, Gauze Ball, Non-woven Ball, Wooden Ayre Spatulas, Disposable Plastic Forceps, Disposable Anoscope, Surgical Set

Munich, CRT2, 2016-04-15

Stefan Preiß Certification Medical Technology

Page 3 of 3

TUV® TÜV SÜD Product Service GmbH — Zertifizierstelle — Fidlerstraße 65 — 80339 München — Seeman

Scanned by CamScanner