

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

Registration No.: DD 60140148 0001

Report No.: 15087412 004

Manufacturer: Ningbo Jenius Polymer Sci-Tech
Co., Ltd.
No. 2112 Ningheng South Road, Hengxi Town
Yinzhou District
Ningbo
315131 Zhejiang
China

Products: Aspects of manufacture concerned with securing and
maintaining sterile conditions:
First Aid Kits, Tourniquets, Bandages, Drapes, Medical
Loops, Disposable Bite Blocks, Medical TPE Covers, Catheter
Fixing Devices

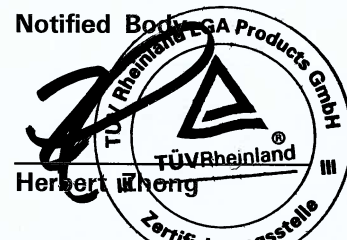
Replaces Approval, Registration No.: DD 60106253 0001

Expiry Date: 2024-05-27

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: 2019-11-18

Date: 2019-11-18



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.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Ningbo Jenius Polymer Sci-Tech
Co., Ltd.**
No. 2112 Ningheng South Road, Hengxi Town
Yinzhou District
Ningbo
315131 Zhejiang
China

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

**Manufacture and Distribution of First Aid Kits,
Tourniquets, Bandages, Drapes, Medical TPE Covers, Medical
Loops, Disposable Bite Blocks, Catheter Fixing Devices**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date: 2019-11-18
Certificate Registration No.: SX 60140152 0001
An audit was performed. Report No.: 15087412 004
This Certificate is valid until: 2022-05-29

Certification Body



Date 2019-11-18



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