

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

Registration No.: DD 60144229 0001

Report No.: 15076053 008

Manufacturer: Zhejiang Bangli Medical
Products Co., Ltd.
No. 118 Yuegui South Road
City West New District
321300 Yongkang City, Zhejiang Province
China

Products: Aspects of manufacture concerned with securing and
maintaining sterile conditions of Wound Plasters, Wound
Dressings, First Aid Kits

Replaces Approval, Registration No.: DD 60097501 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: 2019-11-14

Date: 2019-11-14

Notified Body



Fuxiu Sheng

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

**Zhejiang Bangli Medical
Products Co., Ltd.
No. 118 Yuegui South Road
City West New District
321300 Yongkang City, Zhejiang Province
China**

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

**Manufacture and Distribution of Wound Plasters, Wound
Dressings, Cool Pads, Medical Tapes, First Aid Kits,
Nasal Strips, Self-adhesive Bandages, Eye Patches**

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: 2017-11-26
Certificate Registration No.: SX 60124803 0001
An audit was performed. Report No.: 15076053 005
This Certificate is valid until: 2020-11-25

Certification Body

