

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

Registration No.: DD 60114791 0001

Report No.: 15095312 001

Manufacturer: Zhejiang Anji Huifeng
Surgical Dressings Co., Ltd.
Xiaoshu Industrial Zone,
Anji County, Zhejiang 313307
China

Products:

Aspects of manufacture concerned with securing and
maintaining sterile conditions of Sterile Bandages

Replaces Approval, Registration No.: DD 60082814 0001

Expiry Date: 2021-07-04

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: 2016-10-28

Date: 2016-10-28



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 Anji Huifeng
Surgical Dressings Co., Ltd.**
Xiaoshu Industrial Zone,
Anji County, Zhejiang 313307
China

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

Manufacture and Distribution of Bandages

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: 2019-04-18
Certificate Registration No.: SX 60137298 0001
An audit was performed. Report No.: 15095312 003
This Certificate is valid until: 2019-07-04

Certification Body



Date 2019-04-18



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