

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60101700 0001

Report No.: 15081239 001

Manufacturer: Roosin Medical Co., Ltd.
No. 8 Yuandong Road, Kouan
Town, Gaogang, Taizhou City
225321 Jiangsu Province
China

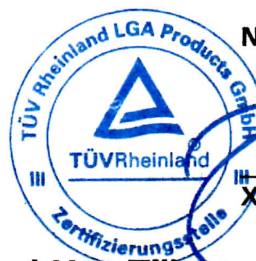
Products: Hydrophilic-Gel Exudate-Absorbent Dressing, Sterile Burn
Gel
Replaces Approval, Registration No.: HD 60087272 0001

Expiry Date: 2020-06-09

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2015-06-10

Date: 2015-06-10



Notified Body

X. Ren

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

Roosin Medical Co., Ltd.
No. 8 Yuandong Road, Kouan
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225321 Jiangsu Province
China

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

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

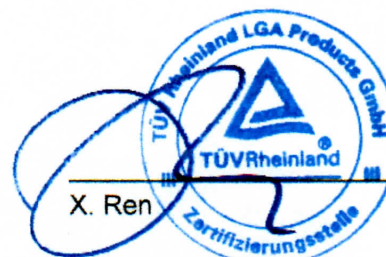
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-08-01
Certificate Registration No.: SX 60131215 0001
An audit was performed. Report No.: 15081239 005
This Certificate is valid until: 2021-06-09

Certification Body



Date 2018-08-01



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

**Attachment to
Certificate**

Registration No.: SX 60131215 0001
Report No.: 15081239 005

Organization: Roosin Medical Co., Ltd.
No. 8 Yuandong Road, Kouan
Town, Gaogang, Taizhou City
225321 Jiangsu Province
China

Scope: Design and Development, Manufacture and Distribution of
Hydrophilic-Gel Exudate-Absorbent Dressing, Sterile Burn
Gel, Silicone Foam Dressings;
Manufacture and Distribution of Cotton Burn Dressing,
Hydrocolloid Wound Dressings, Wound Hydrogel Dressings,
Irrigation Solutions for Eye and Wound Wash, Foam
Dressings, Sterile Dressings, Absorbent Pads, Oil Emulsion
Vaseline Dressings



Date: 2018-08-01

Certification Body

