EC Certificate

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

Registration No.: HD 60149016 0001

Report No.: 15081239 011

Manufacturer:

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

Products:

Hydrophilic-Gel Exudate-Absorbent Dressings, Sterile Burn Gel, Silicone Foam Dressings
Replaces Approval, Registration No.: HD 60146325 0001

Expiry Date: 2024-05-26

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: 2020-05-08

Date: 2020-05-08

Notified Body

Jason Pan

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.