

EC Certificate



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

Registration No.: HD 2185020-1

Manufacturer: Guangdong TiDaKang Medical
Technology Co., Ltd.
1,4 and 5 floor of The
Second Row , No.30 of JinHong Road,
PingNan Industrial Area , SanXiang Town ,
ZhongShan City
528463 Guangdong
P.R. China

Products: Alginate Dressings, Silicone Foam Dressings, Foam Dressings, Silicone
Wound Contact Layers, Negative Pressure Wound Therapy Dressings,
Absorbent Dressings, Amorphous Hydrogel Dressings;
Aspects of manufacture concerned with securing and maintaining sterile
conditions: Catheter Fixing Devices, Adhesive Gas-permeable Films,
Transparent Dressings, Sterile Wound Dressings, Hydrogel Eye Pads,
Hemostasis Dressings

Replaces Approval, Registration No.: HD 60147507 0001

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.

Report No.: 244324083-200

Effective date: 2021-05-25

Expiry date: 2023-05-25

Issue date: 2021-05-25



Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.