

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

Registration No.: DD 60150041 0001

Report No.: 15074137 010

Manufacturer: Idion Medical Co., Ltd.
Quyuan Road 519, Industry
Area, Wukang Town
313200 Deqing, Zhejiang
P.R. China

Products:

Medical Devices

(see attachment for products included)

Replaces Approval Registration No.: DD 60142137 0001

该复印件与原件一致(翻印无效)
The copy is consistent with the original(COPY INVALID)
仅供 LCH medical products 用
only for use
有效期: 2021/9/17 ~ 2022/9/16
Expire date

Expiry Date: 2024-05-26

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: 2021-05-20

Date: 2021-05-20

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60150041 0001
Report No.: 15074137 010

Manufacturer: Idion Medical Co., Ltd.
Quyuan Road 519, Industry
Area, Wukang Town
313200 Deqing, Zhejiang
P.R. China

Products:

X-ray Detectable Gauze Sponges, ABD Pads, Surgical

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Gauze Swabs, Medical Non-woven Swabs, Sterile Non-adherent Pads, Sterile First Aid Dressing Bandages, Sterile Cotton Balls, Sterile Vaginal Speculums, Disposable Medical Scissors, Bowl Liners

For the following medical devices the scope covers only the aspects of manufacture concerned with conformity of products with metrological requirements: Medicine Cups

该复印件与原件一致(翻印无效)
The copy is consistent with the original(COPY INVALID)
仅供: LGA Medical products 用
有效期: 2021/9/7 ~ 2022/9/6
Expiry date

Date: 2021-05-20

Notified Body



Fuxiu Sheng

