





Certificate

No. Q5 065765 0024 Rev. 02

Holder of Certificate: Foosin Medical Supplies Inc., Ltd.

No.20, Xingshan Road

Weihai Torch Hi-tech Science Park 264210 Weihai, Shandong Province PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Design, Development, Production and Sales of Scope of Certificate:

non-absorbable surgical suture with or without needle (model: nylon, supramid nylon, silk, PVDF, PTFE, polyester, polypropylene, Stainless Steel), synthetic absorbable suture (PGA, PGA RAPID, PGLA, PGLA RAPID, PDO, PGCL), non-sterile drilled suture needle, non-sterile synthetic

absorbable suture thread.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 065765 0024 Rev. 02

Report No.: BJ21092601

Valid from: 2021-11-23 Valid until: 2024-11-16

Christoph Dicks 2021-11-23 Date,

Head of Certification/Notified Body





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EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Foosin Medical Supplies Inc., Ltd.

No.20, Xingshan Road, Weihai Torch Hi-tech Science Park, 264210 Weihai, Shandong Province, PEOPLE'S REPUBLIC OF

CHINA

Design, Development, Production and Sales of non-absorbable surgical suture with or without needle (model: nylon, supramid nylon, silk, PVDF, PTFE, polyester, polypropylene, Stainless Steel), synthetic absorbable suture (PGA, PGA RAPID, PGLA, PGLA RAPID, PDO, PGCL), non-sterile drilled suture needle, non-

sterile synthetic absorbable suture thread.

Hangzhou Aipu Medical Products Co., Ltd.

No. 3 Building, Huajiadai No. 288, Xiyou Village, Fuchun Subdistrict, Fuyang District, 311400 Hangzhou City, Zhejiang

Province, PEOPLE'S REPUBLIC OF CHINA

Production of non-absorbable surgical suture with or without

needle (model: nylon, silk, polyester, polypropylene)