ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 062831 0009 Rev. 00

Holder of Certificate: **Fomed Industries Inc**
20 Han Sha Road
Hou Hu District
433115 Qian Jiang City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of**
Sterile and non sterile medical dressings including
Gauze swabs (with/without X-ray)
(For more products, see following pages)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1817101

Valid from: 2019-04-30
Valid until: 2022-04-29

Date, 2019-04-30

Stefan Preiß

Digitally signed by Moldoveanu Ruxanda
Date: 2020.12.04 18:30:04 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Fomed Industries Inc
20 Han Sha Road, Hou Hu District, 433115 Qian Jiang City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

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gauze ball (with/without X-Ray), lap sponges (washed or unwashed), tracheotomy sponges, drain gauze swabs, surgical towels, non-woven swabs, drain non-woven swabs, non-woven ball, non-woven roll, dental cotton roll, dental cotton filled sponges, cotton ball, cotton tipped applicators, gauze and cotton tissues, conforming bandages, W.O.W gauze bandages, fluff gauze roll, absorbent dressing pads (ABD pads), dressing sets, tongue depressors, Medical dressings including gauze rolls (with/without X-ray), absorbent gauzes, Throat packs, cotton filled non-woven sponge, absorbent cotton wools, cotton bandages, Cotton pads, eye pads, triangular bandages, elastic bandages, gauze combine pads, island dressing pads, non adherent pads, transparent pads, stockinette, Medical packing materials including sterilization pouches & reels, tyvek pouches & reels, SMMS non woven wraps, CSR crepe wraps, Paper to paper pouches, Paper to film pouches, film to film pouches, non woven pouches, crepe paper pouches, coated paper rolls, transparent composite film roll, PE laminated paper rolls, Disposable non sterile dental instruments including bite trays, impression trays, fluoride foam trays, saliva ejectors, mixing tips, oral tips, surgical tips, evacuation tips, micro-brushes, dental hand instruments, patient bibs, brush applicators, sterile-soakers, patient bibs clips, apron boxes, cotton roll dispensers, barrier films, mixing bowls, mixing spatulas, impression injectors, Disposable non sterile protective products including face masks (Earloop, Tie-on and Moulded cone), bouffant caps, shoe covers, surgical gowns, isolation gowns, protective clothes, isolated clothes, drapes, latex examination gloves, nitrile examination gloves, latex surgical gloves

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