





Certificate

No. Q6 045790 0024 Rev. 01

Holder of Certificate:

Certification Mark:



Scope of Certificate:

Production and Distribution of Sterile and Non-sterile Gauze Swabs with X-Ray and without X-Ray Detectable, Sterile and Non-sterile Lap Sponges with X-Ray and without X-Ray Detectable, Sterile and Non-sterile Gauze Balls with X-Ray and without X-Ray Detectable, Sterile and Non-sterile Cotton Filled Sponges, Sterile and Non-sterile Non-woven Sponges with X-Ray and without X-Ray Detectable, Sterile and Non-sterile Bandages, Sterile and Non-sterile Absorbent Gauze (Cutting, Folded or Rolled) with X-Ray and without X-Ray Detectable, Adhesive Wound Dressing, Abdominal Dressing Pad, Disposable Non-woven Wearing,

Sterile and Non-sterile Absorbent Cotton,

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.

Dressing Kit

Report No .: SH1901223

Valid from: 2019-08-16 Valid until: 2020-06-15

2019-08-16

1. Punil Stefan Preiß

Head of Certification/Notified Body

Date.



Certificate

No. Q6 045790 0024 Rev. 01

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):

TUV®