



Certificate

No. Q5 046994 0021 Rev. 01

Holder of Certificate: TSK Laboratory, Japan
2-1-5 Hirayanagi-Cho
Tochigi-Shi, Tochigi-Ken
328-0012 JAPAN

Facility(ies): TSK Laboratory, Japan
2-1-5 Hirayanagi-Cho, Tochigi-Shi, Tochigi-Ken, 328-0012 JAPAN

TSK Laboratory, Japan Soja No.1 Factory
1485-11, Soja-Machi, Tochigi-Shi, Tochigi-Ken, 328-0002 JAPAN

TSK Laboratory, Japan Soja Kojo
1510-1, Soja-Machi, Tochigi-Shi, Tochigi-Ken, 328-0002 JAPAN

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Disposable Sterilized Medical Needles, Fixation Device for PEG and Catheter, Cholangiography, Production (Labeling and Packing), and Distribution of Transfusion System

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

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). See also notes overleaf.

Report No.: JN1411189

Valid from: 2020-05-01

Valid until: 2023-04-30

Date, 2020-04-22

Christoph Dicks
Head of Certification/Notified Body