



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 088869 0002 Rev. 04

Holder of Certificate: **TSK Laboratory, Japan**
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 for Cholangiography; Production (Labelling and Packing) and Distribution of Sterile Transfusion System; Design and Development, and Distribution of Disposable Sterilized Medical Syringes**

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 088869 0002 Rev. 04

Report No.: JN200350006201

Valid from: 2025-02-28
Valid until: 2026-04-30

Date, 2025-02-28

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **TSK Laboratory, Japan**
1510-1, Soja-Machi, Tochigi-Shi, Tochigi-Ken, 328-0002 JAPAN

Management, Process Control, Regulatory Affairs, Complaint
Handling and Sales of Disposable Sterilized Medical Needles and
Syringes, Fixation Device for PEG, Catheter for Cholangiography
and Sterile Transfusion System

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

Design and Development, Production, Storage and Distribution of
Disposable Sterilized Medical Needles;
Production (Labelling and Packing), Storage and Distribution of
Sterile Transfusion System;
Design and Development, Storage and Distribution of Fixation
Device for PEG, Catheter for Cholangiography and Disposable
Sterilized Medical Syringes

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

Design and Development, Production, Storage and Distribution of
Disposable Sterilized Medical Needles and Fixation Device for
PEG;
Production (Labelling and Packing), Storage and Distribution of
Sterile Transfusion System;
Design and Development, Storage and Distribution of Catheter for
Cholangiography

TSK Laboratory, Japan Hirayanagi Soko
2-1-5 Hirayanagi-Cho, Tochigi-Shi, Tochigi-Ken, 328-0012 JAPAN

Storage of Parts and Components

-/-