



Certificate

No. Q5 088869 0002 Rev. 01

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 (Labeling and Packing) and Distribution of Sterile Transfusion System; Design and Development, and Distribution of Sterile Syringe**

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 088869 0002 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_088869_0002_Rev.01)

Report No.: **JN2025258**

Valid from: **2023-05-01**

Valid until: **2026-04-30**

Date, 2023-04-25



Christoph Dicks
Head of Certification/Notified Body

Certificate

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

Design and Development, Production (Manufacturing), Storage
and Distribution of Disposable Sterilized Medical Needles;
Design and Development, Storage and Distribution of Fixation
Device for PEG, Catheter for Cholangiography and Sterile Syringe

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

Design and Development, Production (Manufacturing), Storage
and Distribution of Disposable Sterilized Medical Needles and
Fixation Device for PEG;
Production (Labeling 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 and Distribution of Final Products;
Storage of Components

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