



Product Service

Certificate

No. Q5 016328 0143 Rev. 00

Holder of Certificate:



KAWASUMI LABORATORIES, INC.

Shinagawa Intercity Tower B
2-15-2, Konan, Minato-Ku
Tokyo
108-6109, JAPAN

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Disposable Medical Devices for Transfusion, Infusion, Drainage, Injection, Blood Sampling, Blood Tubing Lines, Blood Bag, Hollow Fiber Dialyzers, A.V. Fistula Sets, Plasma Fractionator, Plasma Component Separator and Plasma Separator.

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.:

TH0161018T037

Valid from:

2018-11-01

Valid until:

2021-10-31

Date,

2018-10-25

Stefan Preiß

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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): Kawasumi Laboratories (Thailand) Co., Ltd. (KLT-3)
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