

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2110297-1

Certificate Holder: Fenwal Controls of Japan, Ltd.
5-10 Iidabashi 1-chome
Chiyoda-ku, Tokyo
102-0072 Japan

Scope: Design and Development, Manufacture and Distribution of
Dialysis Systems, Sphygmomanometers and Cryogenic
therapy equipment for pain management

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150279155-301

Effective date: 2024-01-25

Expiry date: 2027-01-24

Issue date: 2024-01-22

Replaces certificate SX 2110297-1 issued 2021-01-21



Nasu Yang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Fenwal Controls of Japan, Ltd. 5-10 Iidabashi 1-chome Chiyoda-ku, Tokyo 102-0072 Japan	Distribution and Corporate management of Dialysis Systems, Sphygmomanometers and Cryogenic therapy equipment for pain management
/02	c/o Fenwal Controls of Japan, Ltd. Nagano Factory 448-1 Toyoshina Azumino-shi, Nagano 399-8205 Japan	Manufacture and Distribution of Dialysis Systems, Sphygmomanometers and Cryogenic therapy equipment for pain management
/03	c/o Fenwal Controls of Japan, Ltd. 232 Tobuki-cho Hachioji-Shi, Tokyo 192-0001 Japan	Design and Development of Dialysis Systems, Sphygmomanometers and Cryogenic therapy equipment for pain management

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