

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 2110297-1

Organization: Fenwal Controls of Japan, Ltd.  
Kyohan Kudan Bldg.  
1-5-10 Iidabashi  
Chiyoda-ku, Tokyo  
102-0072 Japan

Scope: Design and Development, Production 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.: 150228882-320

Effective date: 2021-01-25

Expiry date: 2024-01-24

Issue date: 2021-01-21



  
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The scope of certification also covers the following:

No.	Facility	Scope
/01	Fenwal Controls of Japan, Ltd. Kyohan Kudan Bldg. 1-5-10 Iidabashi Chiyoda-ku, Tokyo 102-0072 Japan	Dialysis Systems, Sphygmomanometers and Cryogenic therapy equipment for pain management
/02	Fenwal Controls of Japan, Ltd. Nagano Factory 448-1 Toyoshina Azumino-shi, Nagano 399-8205 Japan	Production and Distribution of Dialysis Systems, Sphygmomanometers and Cryogenic therapy equipment for pain management
/03	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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