

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2251444-2

Organization: FUJIFILM Healthcare Corporation
2-1, Shintoyofuta,
Kashiwa-shi, Chiba
277-0804 Japan

Scope: Design and Development, Production, Distribution of Instruments, Systems and Accessories for the following Applications: Diagnostic Ultrasound, Bone Densitometry and Sterilized Puncture Adaptor

TÜVRheinland[®]

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.: 150234269-110
Effective date: 2021-02-01
Expiry date: 2023-12-10
Issue date: 2021-02-01



M. Aihara

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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277-0804 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	FUJIFILM Healthcare Corporation Healthcare Ultrasound R&D Center 3-1-1, Higashikoigakubo, Kokubunji-shi, Tokyo, 185-0014 Japan	Design and Development of Instruments, Systems and Accessories for the following Applications: Diagnostic Ultrasound, Bone Densitometry and Sterilized Puncture Adaptor
/02	FUJIFILM Healthcare Manufacturing Corporation Analytical Systems Kashiwa Factory 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan	Production of Instruments, Systems and Accessories for the following Applications: Diagnostic Ultrasound, Bone Densitometry and Sterilized Puncture Adaptor
/03	FUJIFILM Healthcare Manufacturing Corporation Analytical Systems Kashiwa Factory 3-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan	Distribution of Instruments, Systems and Accessories for the following Applications: Diagnostic Ultrasound, Bone Densitometry and Sterilized Puncture Adaptor

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277-0804 Japan

The scope of certification also covers the following:

/04 FUJIFILM Healthcare Corporation
Medical System Operations Group,
Kashiwa
2-1, Shintoyofuta,
Kashiwa-shi, Chiba,
277-0804 Japan

Distribution of Instruments, Systems and
Accessories for the following Applications:
Diagnostic Ultrasound, Bone Densitometry
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