

# 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  
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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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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 and Sterilized Puncture Adaptor
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