

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2067501-1

Organization: Asahi Intecc Co., Ltd. Osaka R&D Center
2-5-2, Ayumino
Izumi-City, Osaka
594-1157 Japan

Scope: Design and Development, Manufacture and Distribution of metallic wires, metallic wire-ropes and metallic coils for medical devices.

Design and Development, Manufacture and Distribution of metallic wire-rope assembly products and metallic coil assembly products for medical devices.

Design and Development, and Manufacture of Microcatheter component, Intravenous catheter component, Sheath introducer component and Other medical tube component.

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.: 150274671-301

Effective date: 2023-07-28

Expiry date: 2024-08-22

Issue date: 2023-07-28



M. Aihara

Michiaki Aihara

TÜV Rheinland LGA Products GmbH
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Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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EN ISO 13485:2016**

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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Asahi Intecc Co., Ltd. Osaka R&D Center 2-5-2, Ayumino Izumi-City, Osaka 594-1157 Japan	Design and Development, Manufacture and Distribution of metallic wires, metallic wire-ropes and metallic coils for medical devices. Design and Development, Manufacture and Distribution of metallic wire-rope assembly products and metallic coil assembly products for medical devices.
/02	c/o Asahi Intecc Co., Ltd. Shizuoka R&D Center 2310-8, Yamashina Fukuroi-city, Shizuoka 437-0066 Japan	Design and Development, and Manufacture of Microcatheter component, Intravenous catheter component, Sheath introducer component and Other medical tube component.

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