

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

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. Tokyo Office 5/F, Shinagawa Front Building, 2-3-13 Konan, Minato-ku, Tokyo 108-0075 Japan	Distribution of metallic wires, metallic wire-ropes and metallic coils for medical devices. Distribution of metallic wire-rope assembly products and metallic coil assembly products for medical devices..

Report No.: 150241187-320
Effective date: 2021-08-23
Expiry date: 2022-08-22
Issue date: 2021-08-11



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Organization: Asahi Intecc Co., Ltd. Osaka R&D Center
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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.

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.

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