



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: ASAHI INTECC CO., LTD.

3-100 Akatsuki-cho,

Seto, Aichi 489-0071 Japan 朝日インテック株式会社

〒489-0071 愛知県 瀬戸市

暁町3番地100

Holds Certificate No: MD 696055

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture and sterilization of catheters and guidewires
Design and manufacture of sterilized endoscopic electrosurgical instruments, surgical instruments, surgical support unit and software for diagnostic system
カテーテル及びガイドワイヤの設計、製造及び滅菌
滅菌済み内視鏡用電気外科手術用器具、手術器具、手術サポートユニット及び診断システム
用ソフトウェアの設計及び製造

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-06-28

Latest Revision Date: 2024-11-05

Effective Date: 2024-12-04 Expiry Date: 2027-12-03

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...making excellence a habit."

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Printed copies can be validated at www.bsigroup.com/ClientDirectory or telephone 045-414-3022

Certificate No:

MD 696055

Location

ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan 朝日インテック株式会社 〒489-0071 愛知県 瀬戸市 暁町3番地100

Registered Activities

Design, manufacture and sterilization of catheters and guidewires
Design and manufacture of sterilized endoscopic electrosurgical instruments, surgical instruments, surgical support unit and software for diagnostic system カテーテル及びガイドワイヤの設計、製造及び滅菌滅菌済み内視鏡用電気外科手術用器具、手術器具、手術サポートユニット及び診断システム用ソフトウェアの設計及び製造



Original Registration Date: 2018-06-28 Effective Date: 2024-12-04 Latest Revision Date: 2024-11-05 Expiry Date: 2027-12-03

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