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Certificate of Registration

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

This is to certify that:

ASAHI INTECC (THAILAND) CO., LTD.

158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi,

Amphur Muang Pathumthani,

Pathumthani

12000 Thailand

Holds Certificate Number: MD 718537

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

Design and development, Manufacturing and EtO sterilization of Catheters, Guidewires and Electrosurgical snares for use in endoscopy.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-10-15

Latest Revision Date: 2019-10-30

Effective Date: 2019-10-15

Expiry Date: 2021-05-01

Page: 1 of 2

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated online.

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +66(2) 2944889-92. Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

Certificate No:

MD 718537

Location

Registered Activities

ASAHI INTECC (THAILAND) CO., LTD. N1 Factory / N2 Factory 142/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand

Design and development, Manufacturing, EtO sterilization, Final packaging, storage and shipping of Catheters, Guidewires and Electrosurgical snares for use in endoscopy.

ASAHI INTECC (THAILAND) CO., LTD. 158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand

Design and development, Manufacturing and EtO sterilization of Catheters, Guidewires and Electrosurgical snares for use in endoscopy.

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