



Certificate of Registration

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

This is to certify that:

ASAHI INTECC HANOI CO., LTD. Thang Long Industrial Park, Dong Anh District, Hanoi, Vietnam

Holds Certificate Number:

MD 718982

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

The design, development, manufacture, EtO sterilization and distribution of Catheters and Guidewires

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-12-28 Latest Revision Date: 2021-07-08 Effective Date: 2021-07-08 Expiry Date: 2024-07-07

Page: 1 of 2



...making excellence a habit.[™]

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Information and Contact: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780 BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

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Location

ASAHI INTECC HANOI CO., LTD. Thang Long Industrial Park, Dong Anh District, Hanoi, Vietnam **Registered Activities**

The design, development, manufacture and distribution activities of Catheter and Guidewire including EtO gas sterilization. The manufacture of PTFE coated component and microbiological testing are performed



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