



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 Effective Date: 2021-07-08 Latest Revision Date: 2021-07-08 Expiry Date: 2024-07-07

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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 <u>online</u>.

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Certificate No: MD 718982

Location Registered Activities

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