

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Filmecc Co., Ltd.
3-99 Akatsuki-cho,
Seto-shi,
Aichi
489-0071
Japan

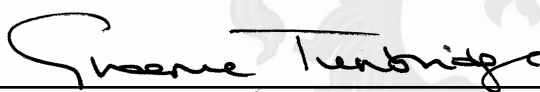
フィルメック株式会社
〒489-0071
愛知県
瀬戸市
暁町3番地99

Holds Certificate No: **MD 802631**

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

Design and Development, Manufacture (Product release), Storage/Logistics and Distribution of Diagnostic and Therapeutic Catheters, Diagnostic and Therapeutic Guidewires and the Peripheral Medical Devices for Diagnostic and Therapeutic Purposes
検査用・処置用カテーテル、検査用・処置用ガイドワイヤー及び検査用・処置用周辺医療機器の設計開発、製造（出荷判定）、保管/物流及び流通

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

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