

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Hudson Respiratory Care
Tecate S. de R.L. de C.V.
A Teleflex Medical Company
Prolongacion Mision Eusebio
Kino No. 1316 Rancho El Descanso
Tecate
Baja California
21478
Mexico

Holds Certificate No:

FM 726156

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

Please see scope page.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2006-04-20

Latest Revision Date: 2021-09-29

Effective Date: 2021-10-22

Expiry Date: 2024-10-21

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Certificate No: **FM 726156**

Registered Scope:

Manufacture of Sterile and non-sterile VPS Stylets, non-sterile VPS G4 consoles, Sterile endotracheal tubes, inspirimeters, sterile electrosurgical devices (pacing wires, electrodes, bipolar cords, suction tubes), Sterile disposable staplers, sterile wire forming, sterile ligation devices (Endo5, disposable appliers), sterile skin retractor devices (derma hooks, raney clips), sterile clip cartridges, non-sterile electronic heaters including brackets, temperature probes and tubing adaptor, sterile Adapt laparoscopic ports, sterile Operative cholangiogram, sterile introducer peritoneal and sterile balloon catheters, sterile capillary drain, sterile inflation syringe, sterile Softwire guidewires, sterile Titanium 4 retrieval basket, Non-sterile Intranasal Mucosal Atomization Devices, and Non-Sterile UroLift Implantable transprostatic tissue retractor system. Manufacture and inspection of OEM product components, including sterile tubing and sterile epidural catheters, and contract manufacture for Non-sterile intravascular catheters, Non-sterile Vascular introducer Kits.



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This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory

To be read in conjunction with the scope above or the attached appendix.