

Certificate of Registration

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

This is to certify that:

Braile Biomédica Indústria, Comércio e Representações Ltda.
Av. Pres. Juscelino Kubitschek de Oliveira, 1505
Jardim Tarraf
São José do Rio Preto
São Paulo
15091-450
Brasil

Holds Certificate Number:

MD 697087

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

Design, development and manufacture of sterile endovascular and gastrointestinal non-active implants, non-active guidewires, implantable cardiac valvular biological prostheses made of tissues of animal origin and reusable accessories, implantable rings for annuloplasty, disposable medical products for cardiac and intraperitoneal surgery, non-sterile active and non-active electronic equipment for cardiac surgery.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-05-14

Latest Revision Date: 2022-01-24

Effective Date: 2022-01-25

Expiry Date: 2025-01-24



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