

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 I
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, manufacture and distribution of non- active sterile implants, instruments and accessories for treatment of cardiovascular defects and peripheral vasculature diseases for the area of cardiology, peripheral vascular medicine and gastrointestinal procedures (non-absorbable, custom- made, synthetic and made from animal tissues).
Design, development, manufacture and distribution of disposable cardiotomy, cardiopulmonary bypass and intraperitoneal perfusion devices.
Design, development, manufacture, distribution, installation and servicing of non- sterile non-active and active equipment and accessories for support in cardiotomy procedures and blood extra-corporeal circulation.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-05-14

Latest Revision Date: 2025-01-06

Effective Date: 2025-01-25

Expiry Date: 2028-01-24

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Certificate No: MD 697087

Location

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

Registered Activities

Design, development, manufacture and distribution of non-active sterile implants, instruments and accessories for treatment of cardiovascular defects and peripheral vasculature diseases for the area of cardiology, peripheral vascular medicine and gastrointestinal procedures (non-absorbable, custom-made, synthetic and made from animal tissues).
Design, development, manufacture and distribution of disposable cardiomy, cardiopulmonary bypass and intraperitoneal perfusion devices.
Design, development, manufacture, distribution, installation and servicing of non-sterile non-active and active equipment and accessories for support in cardiomy procedures and blood extra-corporeal circulation.

Braile Biomédica Indústria Comércio e Representações Ltda.
Rua Pedro Pandim 420
Distrito Industrial
São José do Rio Preto
São Paulo
15035-490
Brasil

Storage of finished devices and distribution.



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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 [online](#).

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

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