

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ITS Material Cirúrgico EIRELI EPP
Rua Dr. João Daniel Hillebrand, 837
Novo Hamburgo
Rio Grande do Sul
93415-520
Brasil

Holds Certificate No:

FM 692691

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

Development, production, commercialization and technical assistance of medical devices to orthopedics and accessories, non-sterile, to: shoulder and elbow; hips and knees; hand and foot; thorax and cardio; buco-maxilla; blades and surgical equipment.

Desenvolvimento, produção, comercialização e assistência técnica de produtos médicos ortopédicos e acessórios, não estéreis, para: ombro e cotovelo; quadril e joelho; mão e pé; tórax e cardio; buco-maxilo; lâminas e equipamentos cirúrgicos.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-02-04

Latest Revision Date: 2019-02-08

Effective Date: 2019-02-04

Expiry Date: 2022-02-03



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