

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Industrias Medicas Sampedro S.A.S.

Carrera 47 100 Sur 40 Bodega 14
Centro Industrial Portal del Sur
Variante a Caldas, Sector La Tablaza
La Estrella, Medellin, Antioquia
Colombia

Holds Certificate Number:

FM 722469

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

Design and production of bone fixation Affinity Distal Radius and Affinity Proximal Tibia (plates and screws) nonactive implantable medical devices.

Diseño y producción de sistemas de fijación ósea Affinity Radio Distal y Affinity Tibia Proximal (placas y tornillos), dispositivos médicos implantables no activos.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2015-10-30

Latest Revision Date: 2022-09-15

Effective Date: 2021-10-30

Expiry Date: 2024-10-29

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