

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Internacional Farmacéutica,
S.A. de C.V.
Carreteraco No. 44
Colonia Parque San Andrés
Coyoacán
C.P. 04040
Ciudad de México
Estado de México
Mexico

Facility ID Number: F000237

Holds Certificate No:

MDSAP 689932

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and Development, Manufacture and Distribution of absorbable and non-absorbable surgical sutures, partially absorbable and non-absorbable surgical mesh, bone wax and temporary unipolar electrodes for pace makers.

Diseño y Desarrollo, fabricación y distribución de suturas quirúrgicas absorbibles y no absorbibles, mallas quirúrgicas no absorbibles y parcialmente absorbibles, cera para huesos y electrodo para marcapaso temporal unipolar epicárdico.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-10-23

Effective Date: 2021-10-23

Expiry Date: 2024-10-22



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 689932**

Location

Internacional Farmacéutica,
S.A. de C.V.
Carreteraco No. 44
Colonia Parque San Andrés
Coyoacán
C.P. 04040
Ciudad de México
Estado de México
Mexico
Facility ID Number: F000237

Registered Activities

Design and Development, Manufacture and Distribution of absorbable and non-absorbable surgical sutures, partially absorbable and non-absorbable surgical mesh, bone wax and temporary unipolar electrodes for pace makers.

Diseño y Desarrollo, fabricación y distribución de suturas quirúrgicas absorbibles y no absorbibles, mallas quirúrgicas no absorbibles y parcialmente absorbibles, cera para huesos y electrodo para marcapaso temporal unipolar epicárdico.

Internacional Farmacéutica
S.A. de C.V.
Circuito de la Industria Poniente
Lote 10-C
Colonia Parque Industrial El Cerrillo
C.P. 52000
Lerma
Estado de México
Mexico
Facility ID Number: F001890

Design and Development, Manufacture and Distribution of absorbable and non-absorbable surgical sutures, partially absorbable and non-absorbable surgical mesh, bone wax and temporary unipolar electrodes for pace makers.

Diseño y Desarrollo, fabricación y distribución de suturas quirúrgicas absorbibles y no absorbibles, mallas quirúrgicas no absorbibles y parcialmente absorbibles, cera para huesos y electrodo para marcapaso temporal unipolar epicárdico.



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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.

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