

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Operaciones de Clase Mundial S.A. de C.V  
Calle Uno Norte No. 720  
Nueva Tijuana  
Tijuana  
Baja California  
C.P. 22435  
Mexico

Holds Certificate No:

**FM 631142**

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

Contractor manufacturing of plastics Injection molding, decorating and assembly of sterile and non sterile products according to customer requirements.

Previous certificate expires on 2/28/2019 (ISO 13485:2003)  
Transition to ISO 13485:2016 recommended 4/16/2019

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-09-30

Latest Revision Date: 2019-05-03

Effective Date: 2019-05-03

Expiry Date: 2020-03-28

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