

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Incipio Devices  
82 Commercial Rd.  
Huntington  
Indiana  
46750  
USA

Holds Certificate No:

**FM 615965**

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

Contract development and manufacturing of non-sterile plastic and metal implants and instruments for the hip, knee, spine, trauma & extremities orthopedic market. Design, manufacturing and distribution of plastic and metal instruments and implants for the hip, knee, spine, trauma & extremities orthopedic market.

Previous certificate expired on 2019-02-28 (ISO 13485:2003 expiration)  
Transition audit ended 2019-04-10



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-11-12

Latest Revision Date: 2019-04-23

Effective Date: 2017-11-12

Expiry Date: 2020-11-11

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Certificate No: **FM 615965**

Location	Registered Activities
Incipio Devices 82 Commercial Rd. Huntington Indiana 46750 USA	Contract development and manufacturing of Non-Sterile Plastic and Metal Implants and Instruments for the Hip, Knee, Spine, Trauma & Extremities Orthopedic market.  Design and commercialization of Medical Devices for the Hip, Knee, Spine, Trauma & Extremities Orthopedic market.
Incipio Devices Av. des Pâquiers 16 St-Blaise 2072 Switzerland	Development and manufacturing of Non-Sterile Plastic and Metal Implants and Instruments for the Hip, Knee, Spine, Trauma & Extremities Orthopedic market. Design and commercialization of Medical Devices for the Hip, Knee, Spine, Trauma & Extremities Orthopedic market.



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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](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.