

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

**Sofic**  
3 Rue Jean-Jacques Rousseau  
Aussillon  
Mazamet Cedex  
81207  
France

Holds Certificate Number: MD 80441

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

The design, development and manufacture of sterile and non-sterile single use devices: medical and dental needles for hypodermic injections; medical and dental safety devices for hypodermic injections and sterile single use handle for protective injection device.

Conception, développement et fabrication de dispositifs stériles ou non stériles, à usage unique: Aiguilles pour injections hypodermiques à usage médical et dentaire; Dispositifs sécurisés pour injections hypodermiques à usage médical et dentaire et poignées stériles à usage unique pour dispositifs d'injections sécurisés.

"In the event of any conflict between the English and French text, the English text shall prevail."

For and on behalf of BSI:

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Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 12/07/2004

Latest Revision Date: 08/07/2016

Effective Date: 12/07/2016

Expiry Date: 28/02/2019

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