

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Ets Marle SAS  
BP 46, ZI rue Lavoisier  
Nogent  
52800  
France

Holds Certificate Number:

**MD 559928**

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

Subcontracted manufacturing for surgical implants and associated instruments

Fabrication en sous-traitance d'implants chirurgicaux et de l'instrumentation ancillaire associée.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2010-07-20

Latest Revision Date: 2019-07-17

Effective Date: 2019-07-20

Expiry Date: 2022-07-19

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Location	Registered Activities
Ets Marle SAS BP 46, ZI rue Lavoisier Nogent 52800 France	Subcontracted manufacturing including Forging, Machining and surface treatment for surgical implants and associated instruments.  Fabrication en sous-traitance d'implants chirurgicaux et de l'instrumentation ancillaire associée, incluant Forge, Usinage et Traitement de Surface
Haute Marne Parachèvement 4 Cité Artisanale Henri Voirpy Sarrey 52140 France	Subcontracted surface treatment including Polishing, Ultrasonic Cleaning and Passivation, Laser Marking for surgical implants and associated instruments.  Traitement de surface en sous-traitance d'implants chirurgicaux et de l'instrumentation ancillaire associée, incluant Polissage, Nettoyage Ultrasons, Passivation et Marquage Laser
SFERIC ZA rue du Courtois prolongée Menars France 41500 France	Subcontracted manufacturing including Machining, Polishing, Ultrasonic Cleaning and Passivation, Laser Marking for surgical implants and associated instruments  Fabrication en sous-traitance d'implants chirurgicaux et de l'instrumentation ancillaire associée, incluant Usinage, Polissage, Nettoyage Ultrasons, Passivation et Marquage Laser
ATS SAS Z.I. de Bruèges - Avenue Monge B.P. 80286 Alès 30106 France	Manufacturing and sale of non-sterile steel parts, surgical implants and ancillaries obtained by investment casting process  Fabrication et vente de pièces, d'implants chirurgicaux et d'ancillaires associés obtenus par fonderie de précision à la cire perdue
Marle Finishing SAS 443, rue René Cassin La Talaudière 42350 France	Subcontracted manufacturing including Machining, Polishing, Anodisation, Ultrasonic Cleaning and Passivation, Laser Marking, HA coating, cleaning before final Packaging, Packaging in Clean Room for surgical implants and associated instruments Subcontracted manufacturing including Polymer 3D printing for instruments  Fabrication en sous-traitance d'implants chirurgicaux et de l'instrumentation ancillaire associée, incluant Usinage, Polissage, Anodisation, Nettoyage Ultrasons, Passivation, Marquage Laser, Revêtement HA, Nettoyage avant Conditionnement Final et Conditionnement en Salle Propre Fabrication en sous-traitance d'ancillaires réalisés en impression 3D

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An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)