

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Arthrex, Inc.**
1370 Creekside Boulevard
Naples
Florida
34108-1945
USA

Holds Certificate No: **FM 84661**

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

The design, development, manufacture, Ethylene Oxide sterilization, service, repair, installation and distribution of sterile and non-sterile metallic, non-metallic, and bio-absorbable implants and associated instrumentation, surgical procedure kits, sutures, total and hemi joint replacement devices and associated instrumentation, arthroscopic and minimally invasive surgical instruments, arthroscopes, electromechanical/electrosurgical ablation, cutting, visualization and fluid management devices and accessories, blood cell separators, centrifuges, and sterile disposable processing sets.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-05-21

Latest Revision Date: 2019-12-18

Effective Date: 2019-11-22

Expiry Date: 2022-11-21



Certificate No: **FM 84661**

Location	Registered Activities
Arthrex, Inc. 1370 Creekside Boulevard Naples Florida 34108-1945 USA	The design and development of sterile and non-sterile metallic, non metallic, and bio-absorbable implants and associated instrumentation, surgical procedure kits, sutures, total and hemi joint replacement devices and associated instrumentation, arthroscopic and minimally invasive surgical instruments, arthroscopes, electromechanical/electrosurgical ablation, cutting, visualization and fluid management devices and accessories, blood cell separators, centrifuges, and sterile disposable processing sets.
Arthrex California, Inc. 168 Brea Canyon Road Walnut California 91789 USA	Design and development, manufacturing and distribution of arthroscopic and minimally invasive surgical instruments.
Arthrex, Inc. 1360 Creekside Boulevard Naples Florida 34108-1945 USA	The design, development, and manufacture of metallic, non-metallic, and bio-absorbable implants, surgical procedure kits, sutures, uni-compartmental knee devices, arthroscopic and minimally invasive surgical instruments, cannula, electromechanical/electrosurgical ablation, cutting and fluid management devices and accessories, blood cell separators, centrifuges, and sterile disposable processing sets.
Arthrex California Technology, Inc. 460 Ward Drive Santa Barbara California 93111 USA	Design and development, manufacturing, servicing, repair, installation and distribution of endoscopes, visualization imaging systems and electromechanical cutting devices and accessories.
Arthrex, Inc. 1265 Creekside Parkway Naples Florida 34108 USA	Customer Service, purchasing, human resources and management information services.
Arthrex Logistics Center 14550 Plantation Road Fort Myers Florida 33912 USA	Inspection of components and finished devices, servicing, repair, loaner set processing, non-sterile packaging and warehousing and distribution.

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To be read in conjunction with the scope above or the attached appendix.

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Location	Registered Activities
Arthrex, Inc. 6875 Arthrex Commerce Drive Ave Maria Florida 34142 USA	Manufacturing, Inspection, Sterile Packaging and Purchasing.
Arthrex GmbH Erwin-Hielscher-Strasse 9 München 81249 Germany	Design and development, purchasing of sterile and non-sterile metallic, non-metallic, and bio-absorbable implants and associated instrumentation, surgical procedure kits, total and hemi joint replacement devices and associated instrumentation, arthroscopic and minimally invasive surgical instruments, arthroscopes, electromechanical/electrosurgical ablation, cutting, visualization and fluid management devices and accessories.
Arthrex GmbH OsKar-von-Miller-Strasse 6 Odelzhausen 85235 Germany	Manufacturing (receiving inspection only), servicing, repair, loaner set processing, installation and distribution of sterile and non-sterile metallic, non-metallic, and bio-absorbable implants and associated instrumentation, surgical procedure kits, total and hemi joint replacement devices and associated instrumentation, arthroscopic and minimally invasive surgical instruments, arthroscopes, electromechanical/electrosurgical ablation, cutting, visualization and fluid management devices and accessories.
Arthrex, Inc. 6861 Arthrex Commerce Drive Ave Maria Florida 34142 USA	Ethylene Oxide Sterilization.
Arthrex Manufacturing, Inc. 130 Arthrex Drive Pendleton South Carolina 29670 USA	Manufacturing of sterile and non-sterile metallic orthopaedics implant and sutures.

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