

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Howmedica Osteonics Corp
325 Corporate Drive
Mahwah
New Jersey
07430
USA

Holds Certificate No:

FM 84568

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

Design, development, manufacture and distribution of sterile and non-sterile orthopaedic implants, bone cements, antibiotic bone cements and synthetic bone substitutes, sterile and non-sterile manual and powered surgical instruments, and surgical cases/trays for the treatment of bone fractures, joint replacement and reconstruction in the area of orthopaedics.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-09-10

Latest Revision Date: 2019-06-26

Effective Date: 2019-06-26

Expiry Date: 2022-06-25

Page: 1 of 2



...making excellence a habit.™

Certificate No: **FM 84568**

Location	Registered Activities
Howmedica Osteonics Corp 325 Corporate Drive Mahwah New Jersey 07430 USA	Design, development, manufacture and distribution of sterile and non-sterile orthopaedic implants, bone cements, antibiotic bone cements and synthetic bone substitutes, sterile and non-sterile manual and powered surgical instruments, and surgical cases/trays for the treatment of bone fractures, joint replacement and reconstruction in the area of orthopaedics.
Stryker Ireland Ltd IDA Industrial Estate Carrigtwohill County Cork Cork Ireland	The manufacture, inspection, sterilization and distribution of sterile and non-sterile orthopaedic implants, prostheses and associated instrumentation for the treatment of bone fractures, and joint replacement.
Howmedica International S de R.L. Raheen Business Park Limerick Ireland	The manufacture, inspection, sterilization and distribution of sterile and non-sterile orthopaedic implants, non-sterile instruments, non-sterile trials, sterile orthopaedic bone cements, antibiotic bone cements and synthetic bone substitutes for the treatment of bone fractures and joint replacement.

Original Registration Date: 2004-09-10

Latest Revision Date: 2019-06-26

Effective Date: 2019-06-26

Expiry Date: 2022-06-25

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.