



## 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 Number: 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. Servicing of orthopaedic surgical instruments, sterilization trays and cases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2004-09-10 Effective Date: 2022-06-26

Latest Revision Date: 2022-09-15 Expiry Date: 2025-06-25

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...making excellence a habit."





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Printed copies can be validated at www.bsigroup.com/ClientDirectory

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

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