

Certificate of Registration

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

This is to certify that:

Howmedica Osteonics Corp
325 Corporate Drive
Mahwah
NJ 07430
USA

Holds Certificate Number:

MD 84569

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

Design, development, manufacture, inspection, sterilization 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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2005-03-11

Latest Revision Date: 2022-09-07

Effective Date: 2022-09-10

Expiry Date: 2025-09-09

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