

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Otto Bock Healthcare LP
3820 West Great Lakes Drive
Salt Lake City
Utah
84120
USA

Holds Certificate No:

FM 39748

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

The design, manufacture, service and distribution of high performance off the shelf and custom advanced composite lower limb prosthetic devices for all levels of amputation. Carbon composite plates for use in foot orthotics, urethane interfaces, suspension sleeves, distal end pads. The service and repair of various medical devices manufactured by Otto Bock Healthcare LP.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 1998-06-05

Latest Revision Date: 2019-07-02

Effective Date: 2019-07-18

Expiry Date: 2022-07-17

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