

Certificate of Registration

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

This is to certify that:

Ortho Club
2165 Earlywood Drive
Franklin
Indiana
46131
USA

Holds Certificate Number:

MD 635660

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

Design, manufacture and distribution of dental impression trays, elastomers, Non-latex intraoral elastics, hooks, elastic bands, orthodontic wires, orthodontic springs. The manufacture and distribution of orthodontic retainers, dental retractors, dental wax, extraoral headgear, facebows, dental polishing strips, positioning aids, dental impression materials, teeth protectors and dental matrix band wedges, orthodontic expanders, ligature wires, expansion screws, orthodontic bands, orthodontic tubes and orthodontic brackets. The distribution of orthodontic hand instruments

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-07-21

Effective Date: 2018-10-04

Latest Revision Date: 2018-10-03

Expiry Date: 2021-10-03



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