

Certificate of Registration

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

This is to certify that:

Optimized Ortho Pty Ltd
17 Bridge Street
Pymble
New South Wales
2073
Australia

Holds Certificate Number:

MD 591112

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

The design and development, manufacture and distribution of software for the area of orthopaedics. The control of manufacture and distribution of non-sterile custom made 3D printed instruments and non-sterile surgical instruments for the area of orthopaedics.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2012-12-04

Latest Revision Date: 2021-12-17

Effective Date: 2021-12-19

Expiry Date: 2024-12-18

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...making excellence a habit.™

Certificate No: **MD 591112**

Location

Optimized Ortho Pty Ltd
17 Bridge Street
Pymble
New South Wales
2073
Australia

Corin (Australia) Pty Ltd
14-16 Suakin Street
Pymble
New South Wales
2073
Australia

Registered Activities

The design and development, manufacture and distribution of software for the area of orthopaedics. The control of manufacture and distribution of non-sterile custom made 3D printed instruments and non-sterile surgical instruments for the area of orthopaedics.

The final inspection of non-sterile custom made 3D printed instruments and non-sterile reusable surgical instruments for the area of orthopaedics.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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