



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Quality Management System Certificate

ISO 13485: 2016

Certificate Number:

MI-2020-CE-10337-1

Issued to:

OrthoCentric Pty Ltd

This is to certify that the Quality Management System for the design, development and manufacture of the devices described below conforms to the relevant provisions of ISO13485:2016.

TGA File Number: [E20-353044](#)

Manufacturer Name: OrthoCentric Pty Ltd

Manufacturer Address: 8 / 28 Barcoo Street
Roseville NSW 2069
AUSTRALIA

Scope of Certification: Design, development, manufacture, final release and dispatch of sterile and non-sterile orthopaedic implants and instruments. Acetabulum trial prosthesis, Femoral head trial prosthesis, Acetabular Shell, Orthopaedic reamer, Acetabulum prosthesis apical hole plug, Non-constrained polyethylene acetabular liner, Ceramic Acetabular Liner, Modular, coated femoral stem prosthesis, Modular, uncoated hip femur prosthesis, Ceramic femoral head prosthesis, Femoral stem centraliser, Orthopaedic broach, Non-bioabsorbable orthopaedic bone screw

Effective Date: 26 September 2022

Expiry Date: 7 December 2023

Name of the authorised person issuing this certificate

**Andrew Bathgate, A/g Director
Devices Quality Audits and Assessments Section
Medical Devices Surveillance Branch**

This certificate is only valid for the period indicated, subject to periodic and satisfactory surveillance audits.
This Certificate remains the property of the Therapeutic Goods Administration and must be returned upon demand.
The authenticity of this Certificate may be verified with the Therapeutic Goods Administration as the issuing authority.