

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Exstent Limited  
12 Miller Court  
Severn Drive  
Tewkesbury  
Gloucestershire  
GL20 8DN  
United Kingdom

Facility ID Number: F006103

Holds Certificate No: **MDSAP 765323**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and Development, and manufacture of custom-made implantable vascular prostheses used to provide external support to the ascending aorta for use by cardiothoracic surgeons.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-01-17

Effective Date: 2023-01-17

Expiry Date: 2025-10-26



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 1

...making excellence a habit.™