

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Occam Design LLC
1201 E Oak St
Louisville
Kentucky
40204
USA

Holds Certificate Number:

FM 561687

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

Contract Manufacturer with in- house Design Engineering, Assembly, Manufacturing, Packaging and Distribution of non-sterile, minimally invasive and/or diagnostic medical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2010-08-13

Latest Revision Date: 2025-06-22

Effective Date: 2025-08-13

Expiry Date: 2028-08-12

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...making excellence a habit.™

Certificate No: FM 561687

Location	Registered Activities
Occam Design LLC 1044 E. Chestnut Street Louisville Kentucky 40204 USA	Storage, and cleanroom manufacturing, manufacture of minimally invasive medical devices that are in a concept phase and may be sterile products in the future.
Occam Design LLC 1201 E Oak St Louisville Kentucky 40204 USA	Contract manufacturer with in house-design engineering, assembly, manufacturing, packaging and distribution of nonsterile, minimally invasive and/or diagnostic medical devices.



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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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