



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Clayens NP USA Inc.

815 Tek Drive
Crystal Lake
Illinois
60014
USA

Holds Certificate Number:

MD 786576

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

The Manufacture and assembly of non- active, non- implantable plastic injection molded medical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-07-12

Latest Revision Date: 2023-07-12

Effective Date: 2023-07-12

Expiry Date: 2026-07-11

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