By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Polyzen, LLC
1041 Classic Road
Apex
North Carolina
27539
USA

Holds Certificate Number: MD 851991

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

Contract development and manufacture of specialized sterile and non-sterile medical components and finished devices, including a variety of protective barrier sheaths, sleeves, bags and pouches.

Transfer from ISOQAR
Certificate number: 1814MED001

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2026-10-13
Effective Date: 2026-10-13
Latest Revision Date: 2026-10-13
Expiry Date: 2027-01-31

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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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