Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Polyzen, LLC
1041 Classic Road
Apex
North Carolina
27539
USA

Holds Certificate No: **FM 851994**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 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: 1814QMS001

For and on behalf of BSI:

Jessica Patel, Senior Vice President, Assurance Americas

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

...making excellence a habit.™

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
A Member of the BSI Group of Companies.