



## *Certificate of Registration*

*This is to certify that the Quality Management System of:*

**Polyzen, LLC**

**1041 Classic Road, Apex, NC 27539**

*has been audited by ISOQAR Inc and conforms to the following Quality Management System Standards:*

**ISO 13485 : 2016**

*The Quality Management System is applicable to:*

**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.**

*This certificate forms part of the approval identified by:*

*Certificate Number: 1814MED001*  
*Initial Registration Date: 2 February 2006*  
*Issue Date: 1 February 2024*  
*Re Issue Date: 15 December 2025*  
*Expiry Date: 31 January 2027*

*Signed:*  
*(on behalf of ISOQAR)*

*Andrew Smith*



*This certificate has been issued by ISOQAR Inc, 24840 Burnt Pine Drive, Suite 5, Bonita Springs, FL 34134, USA and will remain current subject to the company maintaining its system to the required standard(s). This will be monitored regularly by ISOQAR. The use of the ANAB Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate. Further clarification regarding the scope of this certificate and the applicability of the standard requirements may be obtained by consulting the organisation*