



global assurance

This is to certify that the Quality Management System of:

## Moldgenix LLC

354 East Broad Street  
Trumbauersville PA 18970  
United States of America

Central function listed above. See appendix for additional locations

applicable to:

**Contract manufacturing of finished medical devices and plastic injection molded plastic components and assemblies for OEM medical device applications; contract packaging and labelling of non-sterile medical products**

has been assessed and approved by  
National Quality Assurance, U.S.A., against the provisions of:

## ISO 13485:2016

For and on behalf of NQA, USA



ANSI National Accreditation Board

ACCREDITED

ISO/IEC 17021-1

MANAGEMENT SYSTEMS  
CERTIFICATION BODY

Certificate Number: 18163

EAC Code: 14

Certified Since: November 17, 2009

Valid Until: November 17, 2027

Reissued: September 19, 2025

Cycle Issued: November 18, 2024

# Certificate of Registration



global assurance

Appendix to Certificate Number: 18163

## Includes Facilities Located at:

### **Moldgenix LLC**

Certificate Number 18163  
354 East Broad Street  
Trumbauersville PA 18970  
United States of America

Contract manufacturing of finished medical devices and plastic injection molded plastic components and assemblies for OEM medical device applications; contract packaging and labelling of non-sterile medical products

### **Moldgenix LLC**

Certificate Number 18163  
2512 Quakertown Road  
Pennsburg PA 18073  
United States of America

Warehouse and Shipping

nqa

Certified Since: November 17, 2009

Valid Until: November 17, 2027

Reissued: September 19, 2025

Cycle Issued: November 18, 2024



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## Establishment Registration & Device Listing

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**Establishment:**

Moldgenix LLC  
354 East Broad Street  
Trumbauersville, PA 18970  
**Registration Number:** 2529596  
**FEI Number\*:** 1000121324  
**Status:** Active  
**Date Of Registration Status:** 2025

**Owner/Operator:**

Moldgenix LLC  
354 East Broad Street  
PO Box 878  
Trumbauersville, PA US 18970  
**Owner/Operator Number:** 10090559

**Official Correspondent:**

Thomas Houdeshell  
354 East Broad Street  
PO Box 878  
Trumbauersville, PA 18970  
**Phone:** 215-5389613

\* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set