

This is to certify that the Quality Management System of:

Moldgenix LLC

354 East Broad Street Trumbauersville PA 18970 United States of America

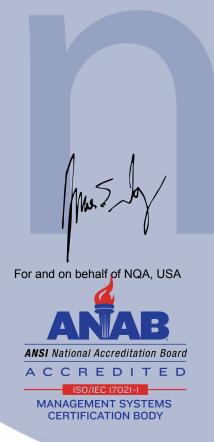
Central function listed above. See appendix for additional locations

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



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

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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

Moldgenix LLC

Certificate Number 18163 2512 Quakertown Road Pennsburg PA 18073 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

Warehouse and Shipping

Certified Since: November 17, 2009

Valid Until: November 17, 2027

Reissued: September 19, 2025

Cycle Issued: November 18, 2024

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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: 2026

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