

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Dynarex Corporation

(FIN F000802)

Main Site: 155 Chestnut Ridge Rd., Suite 2202, Montvale, New Jersey,  
07645, United States

Additional Site: 11 Dynarex Drive, Middletown, New York 10941, United  
States

has been registered by Intertek, an MDSAP recognized auditing  
organization, as conforming to the requirements of:

## ISO 13485:2016

**Canada:** Medical Devices Regulations – Part 1- SOR 98/282

**United States:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A  
to D)

**The management system is applicable to:**

*See Appendix*

*(An appendix containing products manufactured and distributed is also part of this  
certificate of registration)*

*Main site: Management, Quality, Design, Purchasing, Warehouse  
Additional site: Product release, Receiving, Storage, Shipping*

**Certificate Number:**

0209549

**Revision Level:** 00

**Initial Certification Date:**

2025-04-07

**Certification Effective Date:**

2025-04-07

**Certification Expiry Date:**

2028-04-06



**intertek**

**Rathin Grover**

President, Business Assurance

Intertek Testing Services NA, Inc.  
4700 Broadmoor SE, Suite 200  
Kentwood, MI, USA, 49512



# APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

## Dynarex Corporation

This appendix is linked to the Main Certificate #0209549-00 and cannot be shown nor reproduced without it.

Design and manufacture of: sterile packing strips (plain and iodoform), sterile wound dressings (petrolatum dressing), enteral delivery pumps and bag sets, eye cups, polymer patient examination gloves (nitrile), non-rebreathing (CPR shield/masks), and pulse oximeters.

Manufacture of: non-active surgical instruments (vaginal speculas, sterile scalpels, sterile surgical blades, sterile biopsy punches); patient examination gloves; (latex, nitrile, vinyl) and sterile surgical gloves (latex, nitrile); sterile non-active devices for injection, infusion, and transfusion (urological foley catheters, syringes with and without needles, insulin syringes, pen needles, IV administration and extension sets); sterile and non-sterile procedure packs (wound trays, closed circuit foley catheter trays, urethral catheterization trays, irrigation trays); non-active devices for anesthesia, emergency and intensive care - oxygen regulators; wound care devices - sterile lubrication jelly.

Distribution of: general medical, surgical, emergency, and long-term care equipment and supplies; dental devices (covers, sleeves, bibs, impression and bite trays, flow tips, saliva ejectors); durable medical equipment (beds, walkers, canes, tables, mattresses, stands, wheelchairs); diagnostic equipment (blood pressure cuff kits, sphygmomanometers, digital blood pressure monitors, digital thermometers, stethoscopes and); non-active devices for injection, infusion, and transfusion (urological foley catheters, sterile lubricating gel, syringes without needles, syringes with needles, insulin syringes, hypodermic needles, pen needles, IV administration and extension sets); sterile and non sterile bandages and wound dressings (moisturizing wound care hydrogels, waterproof composite dressings, sponges, silver silicone dressings, calcium alginate dressings, hydrocolloid dressings); ECG electrodes; non-active devices for anesthesia, emergency and intensive care (pulse oximeters, manual pulmonary resuscitator bags, tracheal masks, laryngeal masks, oxygen regulators); non-active instruments (vaginal speculas, scalpels, sterile surgical blades, x-ray detectable surgical sponges, biopsy punches, lancets).

