

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

A handwritten signature in black ink that reads "Rathin Grover".

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).

