

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Dynarex Corporation

(FIN F000802)

Main Site: 10 Glenshaw Street, Orangeburg, New York, 10962, USA

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:

*Design and manufacture of:*

*Iodoform Packing Strips; Enteral Delivery Pump Sets; Eye Cups, Pulse Oximeters and CPR masks.*

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

**Certificate Number:**

0085457-05

**Initial Certification Date:**

2019-01-21

**Date of Certification Decision:**

2023-12-04

**Certification Effective Date:**

2023-12-04

**Certification Expiry Date:**

2025-01-20



**intertek**

**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA, Inc.  
900 Chelmsford Street  
Lowell, MA, USA 01851



# 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 #0085457-05 and cannot be shown nor reproduced without it.

Design and manufacture of:

Iodoform Packing Strips; Enteral Delivery Pump Sets; Eye Cups, Pulse Oximeters and CPR masks.

Manufacture of:

Non-Active Instruments (Vaginal Specula, Scalpels, Sterile Surgical Blades, X-Ray Detectable Surgical Sponge, Biopsy Punches, Lancets); Patient Examination Gloves; (Latex, Nitrile, Vinyl) and Sterile Surgical Gloves (Latex, Nitrile).

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); Procedure Packs (Wound Trays, Closed Circuit Foley Catheter Tray, Urethral Catheterization Tray, Irrigation Tray); Bandages and Wound Dressings (Plain packing Strips, Hydrogel Sheets, Waterproof Composite Dressing, Sponges, Silver Foam Dressing, Calcium Alginate Dressing, Petrolatum Dressing, Hydrocolloid Dressings).

Non-active devices for anesthesia, emergency and intensive care (CPR Shields, Finger, Handheld, Manual Pulmonary Resuscitator Bags, Tracheal Masks, Laryngeal Masks, Oxygen Regulators); Catheters and ECG electrodes; Durable Medical Equipment (Beds, Walkers, Canes, Tables, Mattresses, Stands, Wheelchairs); Dental devices (Covers, Sleeves, Bibs, Impression and Bite Trays, Flow Tips, Saliva Ejectors); Diagnostic Equipment (Blood Pressure Cuff Kits, Sphygmomanometers, Digital Blood Pressure Monitors, Digital Thermometers, Stethoscopes).

Distribution of:

General medical, surgical, emergency, and long-term care equipment and supplies.

