

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, and Finger, Handheld, Pediatric Pulse Oximeters.

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

Certificate Number:

0085457-03

Initial Certification Date:

2019-01-21

Date of Certification Decision:

2021-04-06

Issuing Date:

2021-04-06

Valid Until:

2022-01-20



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 #0085457-03 and cannot be shown nor reproduced without it.

Design and manufacture of:

Iodoform Packing Strips; Enteral Delivery Pump Sets; Eye Cups, and Finger, Handheld, Pediatric Pulse Oximeters.

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, CPR masks, 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.

