

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:

*The manufacture and design of Iodoform Packing Strips, Enteral Delivery Pump Sets, Eye Cups,
and Three-Way Stopcocks.*

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

Certificate Number:

0085457

Initial Certification Date:

2019-01-21

Certification Effective Date:

2019-01-21

Certification Expiry Date:

2022-01-20



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 and cannot be shown nor reproduced without it.

The distribution of: Bath chairs and stools, commodes, tub transfer benches, grab bars. Raised toilet seats, toilet safety rails, tub rails. Homecare beds, rails, and mattresses. Air mattresses, pressure pump and gel mattress overlay. Bed and chair alarms. Canes, crutches, walkers, steerable walkers and Rollators. Overbed tables. IV poles. Wheelchairs and cushions. Geri chairs, peddle exercisers, foot stools, and fall mats. Sterile/non-sterile, gauzes, sponges, bandages, dressings, pads, swabsticks, cotton balls and rolls. Iodoform and plain packing strips. Prep pads. Surgical and general use tapes. Wound closure strips. Personal protection: Gowns, coats, jackets, coveralls, pants, caps, gloves, masks, slippers, shoe covers, drapes, cloth stockinettes, barrier sleeves, etc. Nitrile, latex and vinyl surgical and exam gloves. CPR shields. Underpads. Emergency medical devices: tourniquets, splints, blankets, transport units, cot and burn sheets, pillows, hot and cold packs, body immobilizers, punches, scissors, shears, lights, slings, limb holder, gait belt, cervical collars and abdominal binders. Laryngoscope blades and laryngeal mask airways, oral airways, intubating stylettes. Tracheal kits and tube holders. Endotracheal tubes. Body bags & accessories. Patient care disposable devices: drapes, sheets, bedding. bedpans and basins, specimen collection containers, urinals, Sitz Bath, bedside carafe & trays, canisters, cups and various plastics. General dental patient care devices. Dental barrier film, bibs, and tray covers. Wooden tongue depressors, applicators, spoons, cotton tipped applicators. Medicine cups, pill crusher and pouches. General hospital patient care devices. Enema sets, electrodes, tweezers, thermometers, procedure kits and trays. Obstetrical kits. Eye cups. Enteral delivery systems and pump sets. Bulb, irrigation, enteral feeding and piston syringes, syringes with and without needles. IV administration and extension sets. Three Way Stop Cocks and dead end caps. Hypodermic needles with and without syringes. Pen needles. Blood collection tube holders. Sharps containers, Tattoo needles, cartridges, and accessories. Nylon, silk, polypropylene, and polyglycolic sutures. Scalpels and blades. General and urological catheters and kits. Urinary collection/drain bags, specimen cups, emesis bags. Respiratory devices including nasal cannulas, and tubing, bubble humidifier, nebulizers, oxygen masks, oxygen regulators and MPR bags. Suction tubing and canisters. Compressor nebulizers. Vaginal speculum. ECG electrodes. Eye magnet with loop. Diagnostic devices including: sphygmomanometers, stethoscopes, pulse oximeters, blood pressure kits, microscope slides and covers. Ultrasound gels. Sterilization pouches and wraps. Safety lancets, biopsy punch, transducer covers. Germicidal disposable hard surface wipes, antimicrobial hand wipes. Sterile lubricating jelly. Wound cleanser spray (non-antiseptic). Wound care dressings.

