

Certificate US22/00000142

The quality management system of

# Dukal LLC

2 Fleetwood Ct. Ronkonkoma, NY 11779, United States of America

Facility number: F006379

has been assessed and certified as meeting the requirements of

## MDSAP (ISO 13485:2016)

Canada: Medical Device Regulations SOR/98-282, Part 1

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design and Development, Manufacturing, Contract Manufacturing and Distribution of Sterile and Non-Sterile Gauze, Sterile Internal Sponges, Sterile and Non Sterile Non-Woven Sponges, Sterile Wound Dressings, Medical Tape, Sterile Lubricating Jelly, Vaginal Speculum, Sterile and Non Sterile Bandages, Sterile Surgical Drapes, Surgical Masks, Sterile and Non sterile Cotton Tipped Applicators, Sterile and Non sterile OR Towels, Non-sterile Face Shields, Sterile and Non-Sterile Gowns, Non-Sterile Lab Coats, Surgeon Caps, Shoe Covers, Disposable Scrub Wear, Casting Stockinettes and padding, Medical Gloves, Finger Cots, Bone Dust Collector, Stethoscopes, Sphygmomanometers, Blood Pressure Cuffs, Eye Charts, Instrument Stands, Blood Drawing Chairs, IV Stands, Sundry Jars, Tape Measure, Tourniquets, Chair Sleeves, Headrest Covers & Sleeves, Equipment Covers & Sleeves, Tray Sleeves, Barrier Film, Barrier Envelopes, Aspirator Tips, Evacuation Products, Sterilization Pouches/Tape, Patient Bibs and Holders, Denture Cleanser Tablets, Bib Clips, Impression Trays, Fluoride Trays, Micro Applicators, Bendable Brushes, Oral Tips, Prophy Angles, Pre-Bent Dispensing Tips, Toothbrushes, Denture Brushes, Irrigation Syringes, Irrigation Needles, Irrigation Probes.

This certificate is valid from Effective date 2023-08-30 until Expiry date 2025-03-25 and remains valid subject to satisfactory surveillance audits.

Issue 3. Organization certified since 2022-07-28 and first certified by SGS under MDSAP RAC since 2022-10-06



Authorised by

Lynn Henderson

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - [www.sgs.com](http://www.sgs.com)

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