

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 Devices Regulations (SOR/98-282) Part 1 - General  
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

**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from Effective date 2025-03-25 until Expiry date 2028-03-25 and remains valid subject to satisfactory surveillance audits.

Issue 4. Organization certified since 2022-07-28 and first certified by SGS on 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)

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at [www.SGS.com](http://www.SGS.com).



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions | SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



## MDSAP (ISO 13485:2016)

Issue 4

Design and Development, Manufacturing, Contract Manufacturing and Distribution of Sterile Surgical Drapes, Non-sterile Surgical Masks, Sterile and Non-sterile Gowns, Bone Dust Collector, Barrier Film.

Manufacturing, Contract Manufacturing and Distribution of Sterile Wound Dressings, Sterile and Non-Sterile Gauze, Sterile Internal Sponges, Sterile and Non Sterile Non-Woven Sponges, Sterile Lubricating Jelly, Sterile and Non Sterile Bandages, Sterile and Non sterile OR Towels, Vaginal Speculum, Medical Tape.

Distribution of Sterile and Non sterile Cotton Tipped Applicators, Non-sterile Face Shields, Non-Sterile Lab Coats, Surgeon Caps, Shoe Covers, Disposable Scrub Wear, Casting Stockinettes and Padding, Medical Gloves, Finger Cots, Stethoscopes, Sphygmomanometers, Eye Charts, Instrument Stands, Blood Drawing Chairs, IV Stands, Sundry Jars, Tape Measure, Tourniquets, Chair Sleeves, Headrest Covers & Sleeves, Equipment Covers & Sleeves, Tray Sleeves, 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 document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

