




America

CERTIFICATE

No. QS6 091863 0005 Rev. 00

Certificate Holder: **Dukal Corporation**
2 Fleetwood Ct
Ronkonkoma NY 11779
USA

Certification Mark: 

Scope of Certificate: **Manufacture and Distributor of Disposable Medical Products, Sterile and Non-Sterile Gauze, Sterile Internal Sponges, Sterile and Non-Sterile Non-Woven Sponges, Sterile Wound Dressings, Tape, Sterile Lubricating Jelly, Vaginal Speculum; Manufacturer and Distributor of Disposable Medical Products; Apparel, Sterile and Non-Sterile Cotton Tipped Applicator; Sterile and Non-Sterile OR Towels, Sterile and Non-Sterile Bandages, Sterile Surgical Drapes, Surgical Masks; Personal Care, Spa Products and Rehabilitation Products**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **79-101-4871**

Effective Date: **2019-03-26**

Expiry Date: **2022-03-25**

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Date of Issue: 2019-03-26

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com



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