

Crown Aesthetics Receives Medical Device Single Audit Program Certification
Secures Ongoing Distribution in Canada, Australia, Brazil and Japan

January 22, 2020 (Dallas, TX) – Crown Aesthetics, a division of Crown Laboratories and maker of the SkinPen® Precision System, is proud to announce today that it has received Medical Device Single Audit Program (MDSAP) certification after a rigorous audit by BSI (British Standards Institute).

MDSAP was developed by a group of medical device regulators, the International Medical Device Regulators Forum (IMDRF), and allows a single regulatory audit of a medical device manufacturer's quality management system to satisfy the requirements of multiple regulatory authorities. It covers the requirements of ISO 13485:2016 plus Good Manufacturing Practices (GMP) for each applicable regulatory authority. Receiving this certification allows Crown Aesthetics to continue selling SkinPen® into Canada, Australia, Brazil and Japan.

Device manufacturers that choose to participate in MDSAP may expect:

- A more comprehensive approach to quality system auditing and includes the development of an international coalition of countries devoted to pooling resources, technology, and services to enhance the safety and oversight of medical devices worldwide.
- More predictable audits and outcomes through:
 - Grading of nonconformities using objective criteria to characterize the significance of the finding(s)
 - Reporting of audit outcomes using a standard report template
 - Monitoring of the auditing organizations by the participating regulatory authorities
- More efficient marketing authorization applications in countries where a quality management system audit is a prerequisite

Crown Aesthetics continues to lead the market with SkinPen, the first FDA cleared microneedling device. Meeting these standards is validation of Crown Aesthetics' world-class service and unyielding pursuit of quality, safety and efficiency.

"This certification signals our steadfast commitment to best-in-class practices," said Joe Proctor, Crown Aesthetics President. "MDSAP is an efficiency game-changer in a booming industry where patients across the globe are clamoring for safe, natural, non-surgical procedures. The more aligned we are with global compliance, the more effectively and efficiently we can provide our customers products like the SkinPen microneedling device and so many more to come."

About Crown Aesthetics

Crown Aesthetics, a division of Crown Laboratories and premier medical aesthetics company, is dedicated to helping leading aesthetic practices around the world grow their businesses. We do that by delivering dramatic results in rejuvenation and restoration. Our non-invasive innovations – SkinPen®, the first FDA-cleared microneedling device; the post-microneedling protocol SKINFUSE®; the light-activated cream Allumera®; and the platelet-rich plasma systems ProGen™ PRP Versa – act as “gateway” products that draw new consumers to practices. Based in Dallas, Texas, Crown Aesthetics sets industry standards for efficacy, safety, and innovation. As a result, our customers consistently deliver the best aesthetic care in the business. For more information, please visit www.crownaesthetics.com.

About Crown Laboratories, Inc.

Crown Laboratories, Inc., a privately held, fully integrated global skin care company, is committed to developing and providing a diverse portfolio of aesthetic, beauty, and therapeutic skin care products that improve the quality of life for its customers. An innovative company focused on skin science for life, Crown’s unyielding pursuit of delivering therapeutic excellence and enhanced patient outcomes is why it is poised to become a leader in Dermatology and Aesthetics. Crown has been listed on the Inc. 5000 Fastest Growing Privately Held Companies List for six consecutive years and has expanded its distribution to over 25 countries. For more information about Crown or its products, visit www.crownlaboratories.com.

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