Inovytec Achieves MDSAP Certification

Date: June 4, 2026

Inovytec is proud to announce the successful achievement of the Medical Device Single Audit Program (MDSAP) certification. This milestone underscores our unwavering commitment to regulatory excellence and supports our continuous expansion into key global healthcare markets.

By satisfying the rigorous requirements of multiple participating regulatory authorities through a single, comprehensive audit, this certification validates that Inovytec's quality management system meets the highest international standards.

The certification covers compliance with:

- **ISO 13485:2016** Quality management systems for medical devices
- **United States** 21 CFR 820, 21 CFR 803, 21 CFR 806, and 21 CFR 807 (Subparts A-D)
- **Canada** Medical Devices Regulations, Part 1 (SOR/98-282)
- **Australia** TG (MD) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)
- **Japan** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

This achievement further strengthens our ability to serve healthcare providers, emergency medical services, and clinical partners worldwide with safe, reliable, and innovative medical solutions.

Inovytec extends its sincere appreciation to our Quality, Regulatory Affairs, Operations, and cross-functional teams, whose professionalism and dedication made this accomplishment possible. As we continue to scale our global presence, the MDSAP certification provides a powerful foundation for our mission to deliver life-saving technologies wherever they are needed most.

5 Hatidhar Street, Raanana 4366507, Israel | Tel: +972 (0)9 965 6485 | info@inovytec.com | www.inovytec.com