



CERTIFICATE OF REGISTRATION

ProSys International Ltd

Suite 303
165 Broadway
Highland House
Wimbledon, London SW19 1NE UNITED KINGDOM

D-U-N-S ID No. 221836112

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

Design and manufacture of wound dressings for general medicine.
Manufacture of non-invasive bags and catheters for urology, ostomy pouches,
devices for stoma care and faecal management systems for general medicine.



Authorized by



Check Certificate
Status: [here](#)

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC

File Number	A28478	Cycle Start Date	August 30, 2017
Certificate Number	1080.180817	Effective Date	August 17, 2018
Initial Issue Date	August 30, 2017	Expiry Date	July 19, 2020

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory
Services UL, LLC is an MDSAP
Recognized Auditing
Organization**

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



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Additional Regulatory Requirements

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

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