

Hobbs Medical, Inc.

8 Spring St Stafford Springs, Connecticut 06076-1505 UNITED STATES

Facility ID: F006431

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.

The design, development and manufacture of the following products for general medicine: Guide Wires, Injection Needles, Aspirating Needles, Retrieval Baskets, Electrocautery Devices, Balloon Dilators, Balloon Dilator Kits, Biliary and Pancreatic Indwelling Stents, Biliary and Pancreatic Indwelling Stent Kits, Diagnostic Brushes, Cleaning Brushes, Endoscopic Catheters, and Endoscopic Accessories.



Authorized by

Paul Hilgeman Director & Global Industry Leader, Medical CMIT – Medical Regulatory

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Cary Ryman (O)
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Check Certificate Status: <u>here</u>

File Number Certificate Number Initial Issue Date A29034 26698.230407 January 28, 2023 Cycle Start Date Effective Date Expiry Date April 7, 2023 April 7, 2023 April 6, 2026

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.



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

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

CERTIFICATE OF REGISTRATION



Hobbs Medical, Inc.

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Additional Regulatory Requirements

Canada:

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

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (,as applicable)

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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