

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Putnam Medical Corporation

Main Site: 329 Lake Road

Dayville, CT 06241 United States

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Contract Manufacturing to the Medical Device Industry Providing Finished Device Assembly Services such as Specialty Sheaths and Dilators, Catheters, and Delivery Systems

Organization was certified by another Certification Body before 3/28/2023

Certificate Number: 0145654-01

Date of Certification Decision: 2020-11-30

Issuing Date: 2023-11-10

Valid Until: 2026-11-29





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The SCC Accreditation Symbol is an official symbol of the Standards Council of Canada, used under licence.

Calin Moldovean

Intertek Testing Services NA Inc. dba Intertek, 900 Chelmsford Street, Lowell, MA, USA





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

Approved By:

(CO-25) Updated Quality Manual

Description

Quality Manual is being updated to change the title of the Management Representative from VP to QA and RA Manager. Also added the reference to the WI-02-01, Roles and Responsibilities Work Instruction. Routing updated ISO certificate.

Justification

Management Representative has changed from Lisette Grunwell to Holly Opalenik. The Quality Manual needed to reflect the change in title. The Roles and Responsibilities work instruction references ISO 13485:2016 5.5.2 and describes how Quality will function within PMC. Updated ISO certificate is routing. Updated Organization Chart. Updated the SOP-02 to reference WI-02-01.

Assigned To:	Initiated By:	Priority:	Im	pact:	
Holly Opalenik	Holly Opalenik	Urgent	Critical		
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