

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



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

intertek

Calin Moldovean
President

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



ISO 13485 Certificate (DOC-100) Ver. 1

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:

Holly Opalenik

Initiated By:

Holly Opalenik

Priority:

Urgent

Impact:

Critical

Version History:

Author	Effective Date	CO#	Ver.	Status
Holly Opalenik	November 20, 2023 3:10 PM EST	CO-25	1	Published
Holly Opalenik	August 4, 2023 5:19 PM EDT	Not Available	0	Superseded