

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Paragon Medical Inc.

Main Site: 8 Matchett Drive

Pierceton, Indiana, 46562, United States

Additional sites: Refer to Appendix

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

ISO 13485:2016

The management system is applicable to:

The design and production of instrument delivery systems; the production of extruded polymer sheets; and the design and production of sterile and non-sterile custom surgical instrumentation, trials, and implants.

Main site: The production of custom surgical instrumentation, trials, and implants.

(An appendix is also part of this certificate of registration)

Organization was certified by another Certification Body before 8/19/2020

Certificate Number:

0104445-07

Date of Certification Decision:

23 December 2024

Issuing Date:

23 December 2024

Valid Until:

2 January 2028



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

intertek

A handwritten signature in black ink, appearing to read "Calin Moldovean".

Calin Moldovean
President

Intertek Testing Services NA, Inc. dba Intertek
4700 Broadmoor SE, Suite 200
Kentwood, Michigan 49512, United States



APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

Paragon Medical Inc.

This appendix is linked to the Main Certificate #0104445-07 and cannot be shown nor reproduced without it.

Additional site1: 22 Pequignot Dr., Pierceton, Indiana, 46562, United States

Scope: The design and production of sterile and non-sterile surgical instrumentation, trials, implants, non-sterile instrument delivery systems and the production of extruded polymer sheets.

Additional site2: 3507 Commerce Drive, Warsaw, Indiana 46580 United States

Scope: 3-D printing of medical implants, instruments and components

Additional site3: 24 Pequignot Dr., Pierceton, Indiana, 46562, United States

Scope: 3-D printing of medical implants, instruments and components

