

This is to certify that the Quality Management System of:

## **Kelpac Medical Ltd., A Spectrum Plastics Group Company**

IDA Business & Technology Park Srah, Tullamore, Co. Offaly Ireland

Central function listed above. See appendix for additional locations

applicable to:

Design, development and contract manufacture of finished devices, extruded tubing, catheter components and sub assembly solutions. Contract sterilization for medical device applications.

has been assessed and approved by National Quality Assurance, U.S.A., against the provisions of:

ISO 13485:2016

Mus Joy

For and on behalf of NQA, USA



Certificate Number: 15367

EAC Code: 17, 14 Certified Since: January 9, 2015

Valid Until: January 7, 2024 Reissued: January 8, 2021

Cycle Issued: January 8, 2021



Appendix to Certificate Number: 15367

## **Includes Facilities Located at:**

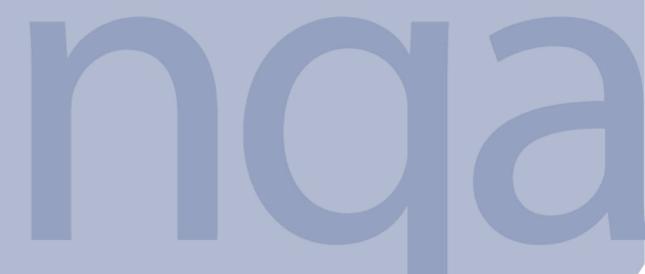
Kelpac Medical Ltd., A Spectrum Plastics Group Company

Certificate Number 15367
IDA Business & Technology Park
Srah, Tullamore,
Co. Offaly
Ireland

Design, development and contract manufacture of finished devices, extruded tubing, catheter components and sub assembly solutions. Contract sterilization for medical device applications.

Earnan Biomedical Limited, A Spectrum Plastics Group Company

Certificate Number 15367 Kilmacree, Drinagh Wexford Ireland Prototyping and development of balloons, catheter components and feasibility devices.



Certified Since: January 9, 2015

Valid Until: January 7, 2024

Reissued: January 8, 2021

Cycle Issued: January 8, 2021

Page 2 of 2