## nqa

This is to certify that the Quality Management System of:

## Kelpac Medical Ltd., A Spectrum Plastics Group Company <br> IDA Business \& Technology Park <br> Srah, Tullamore, <br> Co. Offaly <br> 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

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

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## nqa global assurance

Appendix to Certificate Number: 15367

## Includes Facilities Located at:

## Kelpac Medical Ltd., A Spectrum Plastics

 Group CompanyCertificate Number 15367
IDA Business \& Technology Park
Srah, Tullamore,
Co. Offaly
Ireland

Earnan Biomedical Limited, A Spectrum Plastics Group Company
Certificate Number 15367
Kilmacree, Drinagh
Wexford
Ireland

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

Prototyping and development of balloons, catheter components and feasibility devices.


Certified Since: January 9, 2015
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