



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

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



Certificate of Registration



nqa global assurance

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.



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