nqa global assurance

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

applicable to:

Contract Development and Manufacturing of medical devices, sub-assemblies, components, and associated activities.

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, 2027 Reissued: January 8, 2024 Cycle Issued: January 8, 2024

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This approval is subject to the company maintaining its system to the required standard, which will be monitored by NQA, USA, 289 Great Road, Suite 105, Acton, MA 01720, an accredited organization under the ANSI National Accreditation Board.