nga global assurance

This is to certify that the Quality Management System of:

# Kelpac Medical part of Spectrum Plastics Group

1500 Park Way Global Park La Aurora de Heredia Republic of Costa Rica

Central function listed above. See appendix for additional locations

applicable to:

Manufacture of blown film products including on bag printing and conversion for medical device application and manufacture of tubing and sub-assemblies for medical devices under cleanroom conditions.

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: 16706 EAC Code: 17, 14 Certified Since: December 9, 2016 Valid Until: December 8, 2025 Reissued: December 9, 2022 Cycle Issued: December 9, 2022

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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.

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Appendix to Certificate Number: 16706

### **Includes Facilities Located at:**

#### Kelpac Medical part of Spectrum Plastics Group

Certificate Number 16706 1500 Park Way Global Park La Aurora de Heredia Republic of Costa Rica

### Kelpac Medical part of Spectrum Plastics

Group Certificate Number 16706 1200 Park Way Global Park La Aurora de Heredia Republic of Costa Rica Manufacture of blown film products including on bag printing and conversion for medical device application and manufacture of tubing and sub-assemblies for medical devices under cleanroom conditions.

Warehousing of raw materials, finished goods, overflow/contingency JIT product.

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