

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:

Contract manufacture of blown film products including on bag printing and conversion for medical device application and contract manufacture of tubing, sub-assemblies and solvent bonding of medical devices and Manufacture of healthcare packaging include breather bags, pouches, lids, and roll stock from various substrates according to customer requirements

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, 2028 Reissued: December 9, 2025

Cycle Issued: December 9, 2025

Page 1 of 2



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 1203 Park Way Global Park, La Aurora, Ulloa District Heredia Canton Hereda Province Republic of Costa Rica

### Kelpac Medical part of Spectrum Plastics Group

Certificate Number 16706 1200 Parkway Global Park La Aurora, Ulloa District Heredia Canton, Heredia Province Republic of Costa Rica Contract manufacture of blown film products including on bag printing and conversion for medical device application and contract manufacture of tubing, sub-assemblies and solvent bonding of medical devices and Manufacture of healthcare packaging include breather bags, pouches, lids, and roll stock from various substrates according to customer requirements

Solvent bonding, bag and pouch manufacturing

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

Certified Since: December 9, 2016

Valid Until: December 8, 2028

Reissued: December 9, 2025

Cycle Issued: December 9, 2025

Page 2 of 2