



This is to certify that the Quality Management System of:

Kelpac Medical, A Spectrum Plastics Company

1000 Calle Recodo
San Clemente CA 92673
United States of America

Central function listed above. See appendix for additional locations

applicable to:

To provide development, engineering and manufacturing solutions for medical grade tubing applications under controlled manufacturing 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: 17739
EAC Code: 14
Certified Since: September 12, 2018
Valid Until: September 11, 2024
Reissued: September 12, 2021
Cycle Issued: September 12, 2021



Certificate of Registration



global assurance

Appendix to Certificate Number: 17739

Includes Facilities Located at:

Kelpac Medical, A Spectrum Plastics Company

Certificate Number 17739
1000 Calle Recodo
San Clemente CA 92673
United States of America

To provide development, engineering and manufacturing solutions for medical grade tubing applications under controlled manufacturing conditions

Kelpac Medical, A Spectrum Plastics Company

Certificate Number 17739
1440 N. Industrial Park Blvd.
Nogales, AZ 85621
United States of America

To provide development, engineering and manufacturing solutions for medical device applications under class 8 clean room conditions



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