nqa global assurance

This is to certify that the Quality Management System of:

## Bioseal

167 West Orangethorpe Ave Placentia CA 92870 United States of America

Central function listed above. See appendix for additional locations

applicable to:

Design, manufacturing and distribution of Duraholder, sterile single use items and convenience kits, as well as contract manufactured private label products and assembly and contract packaging of OEM medical devices.

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: 18316 EAC Code: 29 Certified Since: September 12, 2019 Valid Until: September 11, 2025 Reissued: September 12, 2022 Cycle Issued: September 12, 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.

Appendix to Certificate Number: 18316

## **Includes Facilities Located at:**

### Bioseal

Certificate Number 18316 167 West Orangethorpe Ave Placentia CA 92870 United States of America

#### Bioseal

Certificate Number 18316 159 West Orangethorpe Ave Placentia CA 92870 United States of America Design, manufacturing and distribution of Duraholder, sterile single use items and convenience kits, as well as contract manufactured private label products and assembly and contract packaging of OEM medical devices.

Manufacturing and warehousing.

Certified Since: September 12, 2019 Valid Until: September 11, 2025 Reissued: September 12, 2022 Cycle Issued: September 12, 2022

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