



**Orion Registrar, Inc.**

**Thorough and Fair Auditing**

# Certificate of Certification

**Orion Registrar, Inc. - USA**

*This is to certify the Quality Management System of:*

**REPLIGEN CORPORATION,  
Operating Room Disposables Division  
3400 Royalty Row  
Irving, TX 75062  
USA**

*Has been assessed by Orion Registrar and found to be in compliance with the following Quality Standard:*

**EN ISO 13485:2016**

*The Quality Management System is applicable to:*

**Contract Manufacturing of Operating Room Disposable Products and the Development, Manufacturing and Sales of Sterile and Non-sterile Equipment Drapes, Compression Bandages, Stockinettes and Specialty Soft Goods.**

The Certification period is from

**June 1, 2018 to July 15, 2021**

*This certification is subject to the company maintaining its system to the required standard, and applicable exceptions, which will be monitored by Orion.*

Client ID: 4043    Certificate ID: 1015414A



  
*Paul M. Burck*    November 9, 2018  
**Paul M. Burck, President**    *Date*

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To authenticate this certificate, please visit: <http://www.orion4value.com/about-orion/registered-companies/>