

Certificate of Certification

This is to certify the Quality Management System of:

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

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

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 17, 2021 to July 15, 2024

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: 1022363





