



Orion Registrar, Inc.
Thorough and Fair Auditing

Certificate of Certification

This is to certify the Quality Management System of:

Eldon James Corp.
3486 Precision Drive
Fort Collins, CO 80528 USA

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:

Design, manufacture, assembly, packaging and sales of PVC-Free medical components that meet or exceed the statutory and regulatory requirements of our customers including tubing and connectors made of PVC-Free plastics and stainless steel. All products can be assembled and manufactured within our class 7 Cleanrooms.

The Certification period is from

January 20, 2023 to November 26, 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: 1407

Certificate ID: 1026473

Central Function Site - For Additional Site(s) See Appendix




Paul M. Burck, President January 24, 2023
Date



Orion Registrar, Inc.
Thorough and Fair Auditing

Additional Sites - Appendix
Eldon James Corp.
ISO 13485:2016

Client ID: 1407 Certificate ID: 1026473

January 20, 2023 to November 26, 2024

Location	Address	Scope
Eldon James Corp. (Campus)	3420 Precision Drive Fort Collins, CO 80528 USA	Same as Central Function Site
Eldon James Corp.	10325 E 47th Ave Denver, CO 80238 USA	Design, manufacture, assembly, packaging and sales of PVC-Free medical components that meet or exceed the statutory and regulatory requirements of our customers including tubing and connectors made of PVC-Free plastics and stainless steel. All products can be assembled and manufactured within our class 7 Cleanroom.