

Certificate

Certificate No.: MD 2218345-12

Manufacturer: **Ansell Healthcare Products, LLC**

2301 Robb Drive
Reno NV 89523
USA

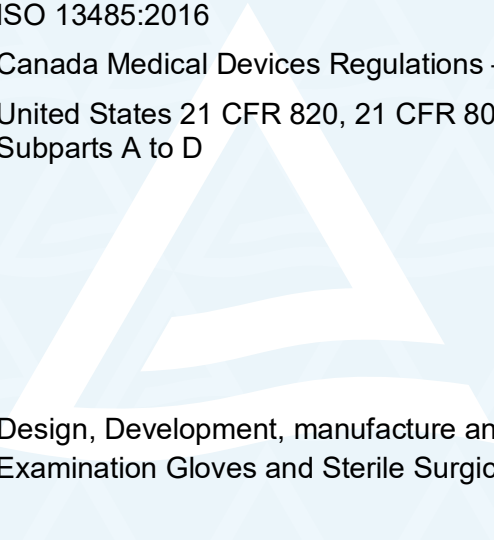
REPs Facility ID: F003780

Certification criteria: ISO 13485:2016

Canada Medical Devices Regulations – Part 1 – SOR 98/282

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design, Development, manufacture and distribution of Non-sterile
Examination Gloves and Sterile Surgical Gloves


TÜV Rheinland[®]

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 234180401-30

Issue Date: 2022-04-05

Effective Date: 2022-04-05

Expiry Date: 2025-01-11



Certification officer: Dipl.-Ing. Sebastiano Pane
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/0000000000?locale=en
or calling 1-888-743-4652.

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The scope of certification includes the following additional sites:

No.	Location	Scope
/01	Ansell Healthcare Products, LLC 2301 Robb Drive Reno NV 89523 USA REPs ID: F003780	Activities associated with design and development, manufacture and distribution.
/02	Ansell Healthcare Products, LLC 9460 North Virginia St., Bldg. B Reno NV 89506 USA REPs ID: F003852	Activities associated with distribution
/03	Ansell Healthcare Products, LLC 1186 Arbor Drive Romeoville IL 60446 USA REPs ID: F003854	Activities associated with distribution

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