

Certificate

Certificate No.: MD 1429047-1-1

Manufacturer: Ferris Mfg. Corp.

5133 Northeast Parkway Fort Worth TX 76106

USA

REPs Facility ID: F004238

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance

Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC

ANVISA n. 67/2009

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

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD

Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 -

Subparts A to D

Scope: Design and Development, Manufacture, and Distribution of Wound

Care Dressings

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.: 234206759-30

 Issue Date:
 2023-12-12

 Effective Date:
 2023-12-24

Expiry Date: 2026-12-23



Contification officers Dial larg Schoolings Day

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/9000010787?locale=en or calling 1-888-743-4652.

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