

Certificate

Certificate No.: MD 234159876-12

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. 16/2013, RDC ANVISA n. 23/2012, 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

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.: 234177254-12

Issue Date: 2022-02-20

Effective Date: 2022-02-20

Expiry Date: 2023-12-23




Certification officer: Sandor Juhasz
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.