MDSAP CERTIFICATE

Certificate No. 007.22-1/MDSAP

This is to certify that

VALMED SRL

Via dell'Industria 3, Tovo di Sant'Agata, Sondrio, 23030, Italy

Facility ID: F006591

Operates a

Quality Management System, which complies with the requirements of ISO 13485:2016 and with the requirements of the following Regulatory Authorities

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 Device Regulations – Part 1 - SOR/98-282

United States:
• 21 CFR Part 803
• 21 CFR Part 806
• 21 CFR Part 807 - Subparts A to D
• 21 CFR Part 820

for the following scope of certification

The design and development, manufacture of sterile enteral and parenteral feeding bags, sterile intravenous (IV) infusion sets and transfusion sets for the area of general hospital

Reference to IMQ files Nos.:
DM22-0083780-01; DM23-0094037-01

Effective Date:	2023-11-13
Expiry Date:	2026-11-12
Issued on:	2023-11-13

IMQ
Fulvio Giorgi – IMQ MDSAP Director

IMQ is an authorized MDSAP Auditing Organization

This MDSAP certificate is subjected to the provisions laid down by IMQ in the "Regulation for Conformity Assessment Activities pursuant to Medical Device Single Audit Program (MDSAP) for which IMQ operates as Auditing Organization". The validity of this certificate can be verified by writing to MDSAP@imq.it.