

Certificate US19/819943313

The quality management system of

PriMed Instruments Inc.

1080 Tristar Drive, Unit 14, Mississauga, Ontario, L5T 1P1, Canada

Facility Identification Number: F002999

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP (ISO 13485:2016)

Australia:

Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

United States:

21 CFR Part 803 - Medical Device Reporting

21 CFR Part 806 - Reports of Corrections and Removals

21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing

21 CFR Part 820 - Quality System Regulation

For the following activities and devices

Design, manufacture and distribution of endoscopic instruments (including non-sterile reusable biopsy forceps, sterile disposable endoscopic biopsy forceps and retrieval devices, non-sterile reusable and disposable cleaning brushes and non-sterile tissue collection devices).

Provision of manufacturing services for catheter subassembly.

This certificate is valid from Effective Date: 10 August 2022 until Expiry Date: 09 August 2025 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 09 August 2025

Issue 3. Certified since 13 August 2019.

Authorised by



Lynn Henderson

Knowledge

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