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

L. Henderson

Lynn Henderson
Knowledge
Global Head of Medical Device Operations

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