

Certificate Number US19/819943313



The management system of

PriMed Instruments Inc.

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

Dun & Bradstreet D-U-N-S identification number : 25-449-1293

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 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

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

United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2019-08-20 until Expiry Date: 2022-08-12
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2022-08-12
Issue 2. Certified since 2019-08-13

Authorised by J Hall
Business Manager



Jonathan M. Hall

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MDSAP M2

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Certificate Number US19/819943313, continued

SGS

The management system of

PriMed Instruments Inc.
MDSAP (ISO 13485:2016)

Issue 1



Detailed scope

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.

Australia:

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

Provision of manufacturing services for catheter subassembly.

Canada:

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.



USA:

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).

Provision of manufacturing services for catheter subassembly.



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