# Declaration of Product Performance Effectiveness

## Product Family: Disposable Channel Cleaning Brush (DCCB) Kits

PriMed Instruments' Single-Use Endoscope Cleaning Brush Kits 9142, 9140, 9122, 9155 and 9199 contains channel brushes that have been validated for cleaning efficacy in accordance with AAMI TIR30. Refer to the Table No. 1 for the part number of each channel and suction well/valve brush in the kit.

Testing of channel brush models 9115, 9190 and 9192 (DART® Push and Pull Triple Headed Channel Brush) were successfully completed according to instructions provided in the IFU and requirements outlined in AAMI TIR30. In the studies conducted by SPS Medical[1][2] and Highpower Vtls[3], the results verify that a protein level of less than 6.4$\mu g/cm^2$ was achieved on the endoscope channels when using PriMed Instrument Inc. and leading competitors cleaning brushes (such as Olympus and Pentax), demonstrating each device to be efficacious in removing gross amounts of soil. A Protein level of less than 6.4$\mu g/cm^2$ is required by AAMI TIR30 after cleaning, in order to allow the disinfection/sterilization process to achieve the proper sterility assurance level. SPS Medical and Highpower could not find any significant difference in the total percentage of soil removed between PriMed Instruments Inc. and the leading competitors' brushes.

Since channel brushes 9115, 9190 and 9192 have been successfully validated, other brushes that have identical brush ends and minimum channel size compatibility are also deem validated. For example, brush 9194 which have identical brush end and minimum channel size requirement as the 9190 is confirmed to be validated given the successfully validation of 9190.

The suction well or valve brush found in the kit listed on Table No. 1 are designed to properly fit and clean common port hole sizes found in the endoscope. These ports present a lower risk of patient cross-contamination and cleaning of them can be verify by visual inspection. As such, cleaning efficacy validation was not conducted for these suction well or valve brushes.

**Table No. 1: Description of Brush Kits**

| PRODUCT NUMBER | DESCRIPTION |
|---|---|
| 9199 | Channel & Suction Well Cleaning Brush Kit (9190 + 9990) – 2 pieces |
| 9155 | Channel & Suction Well/Valve Cleaning Brush Kit (9115 + 9992) – 2 pieces |
| 9142 | Channel & Suction Well/Valve Cleaning Brush Kit (9194 + 9992) – 2 pieces |
| 9140 | Channel & Suction Well Cleaning Brush Kit (9194 + 9990) – 2 pieces |
| 9122 | Channel & Suction Well/Valve Cleaning Brush Kit (9192 + 9992) – 2 pieces |



PRIMED INSTRUMENTS INC.
1080 Tristar Drive • Unit 14 • Mississauga • Ontario L5T 1P1 • Canada
phone 905 565 0565 • fax 905 565 05665 • www.primedinstruments.com

Date of Declaration: May 3, 2018

Declared at: Mississauga, Ontario, Canada

Authorized By (Signature): [signature]

Authorized By (Print): DONG LY

Manager of Regulatory Affairs, PriMed Instruments Inc.

References:

[1]SPS Medical Study No. 1205-159 Protocol and Final Report titled "PriMed Instruments Inc. Comparative Cleaning Study for Disposable Channel Cleaning Brush Stage 1." Cleaning efficacy validation of 9190 & 9192 completed on Jul. 23, 2012.

[2]SPS Medical Study No. 1209-322 Protocol and Final Report titled "PriMed Instruments Inc. Comparative Cleaning Study for Disposable Channel Cleaning Brush Stage 2." Cleaning efficacy validation of 9115 & 9192 completed on Oct. 23, 2012.

[3]Highpower Validation Testing & Lab Services Study No. 1712-821 Protocol and Final Report titled "PriMed Instruments Inc. Comparative Cleaning Study for Disposable Channel Cleaning Brushes." Cleaning efficacy revalidation of 9190 changed to mostly single-fill bristles was completed on Feb. 14, 2018



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