



## Declaration of Product Performance Effectiveness

**Product Family: Disposable Channel Cleaning Brush (DCCB)**  
**Product Model: 9253 aka 9291<sup>(3)</sup>, SuperDART® Pull Through Brush w/Squeegee Wipers for endoscope channels with diameter sizes of 2.0mm and 2.8mm and overall length of 48 inches (1210mm) and 73 inches (1850mm) respectively.**

PriMed Instruments' SuperDART® disposable channel cleaning brush DCCB model 9291 was tested and found to have met and exceeded AAMI TIR30<sup>(2)</sup> requirement for manual cleaning efficacy. Testing conducted by an ISO 17025 accredited third party lab, Highpower VtIs<sup>(1)</sup>, have concluded that a protein level of less than 6.4µg/cm<sup>2</sup> was easily achieved when using the SuperDART® brush after only **ONE (1) PASS** through of the inoculated endoscope channels. A Protein level of less than 6.4µg/cm<sup>2</sup> is required by AAMI TIR30 after cleaning, in order to allow the disinfection/sterilization processes to achieve the proper sterility assurance level. Please see the summary result in Table 1 below.

**Table No. 1: Protein analysis result for SuperDART® after only ONE (1) PASS through the worn<sup>(A)</sup> and inoculated endoscope channels.**

Study No.	Brush Model	Brush Feature	Channel Model	Avg. Protein Level After Cleaning (µg/cm <sup>2</sup> )	Soil Removal
2210-652 <sup>(1)</sup>	PriMed Inst. 9291 <b>SuperDART®</b>	Double Nylon Heads w/Squeegee	46-0028-00 2.8mm x 73"	0.012	99.9994%
	PriMed Inst. 9291 <b>SuperDART®</b>	Double Nylon Heads w/Squeegee	46-0020-00 2.0mm x 48"	0.000	100%

The negative sample control was less than the assay quantitation limit of 0.5µg/mL.  
The positive sample control was greater than or equal to the assay quantitation limit of 0.5µg/mL.

Based on the above results we declare that the SuperDART® Product Model 9253 aka 9291<sup>(3)</sup> is effective in cleaning the endoscope channels with inner diameter size of 2.0mm – 2.8mm and up to 73 inches (1850mm) in length in **ONE (1) PASS** through the channel.

### NOTE:

<sup>A</sup> Study No. 2210-652 was conducted using worn channels to more accurately simulate real world conditions. The channels were exposed to one-thousand (1000) biopsy forceps insertions in order to recreate micro scratches that are always present in endoscopes' channels. A scratched channel will retain more contaminants and presents a more challenging condition for the validation of the brush efficacy when compared to an unused channel.

Author/Reviewer of Declaration:

Dong Ly, Manager of RA & PD, PriMed Instruments Inc.

Reviewed By (Signature):

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Initial: DL



Date of Declaration:

June 21, 2023

Declared at:

Mississauga, Ontario, Canada

Approved By (Print):

Jack Krzyzanowski, General Manager, PriMed Instruments Inc.

Approved By (Signature):

A handwritten signature in black ink, appearing to read "J. Krzyzanowski", is written over a horizontal line.

References:

<sup>1</sup> Highpower Validation Testing & Lab Services Study No. 2210-652 Protocol and Final Report titled "Manual Cleaning Validation of Worn GI Endoscope Channels when using the PriMed Instruments 9291 SuperDART® Brush Protein Analysis." Cleaning efficacy validation of 9291 was completed on Dec. 12, 2022.

<sup>2</sup> A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices (AAMI TIR30:2011/®2016). In the case of validating the efficacy of the disposable channel cleaning brush, the test channel is the reusable medical device.

<sup>3</sup> PriMed Instruments' Quality Memo QM-7.5.2-M23, Change P/N from 9291 to 9253. Authorized by GM (JK) on Jun. 21, 2023.

SuperDART® is a registered trademark of PriMed Instruments Inc.

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