



Declaration of Product Performance Effectiveness

Product Family: Disposable Channel Cleaning Brush (DCCB)
Product Model: 9292, SuperDART® Triple Action Pull Through Brush w/Squeegee Wipers for endoscope channels with diameter sizes of 2.8mm and 4.2mm and 73 inches (1854mm) in length

PriMed Instruments' SuperDART® disposable channel cleaning brush DCCB model 9292 was tested and found to have met and exceeded AAMI TIR30 requirement for manual cleaning efficacy. Testing conducted by an ISO 17025 accredited third party lab, Highpower VtIs⁽¹⁾, have concluded that a protein level of less than 6.4µg/cm² 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/cm² 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^(A) and inoculated endoscope channels.

Study No.	Brush Model	Brush Feature	Channel Model	Avg. Protein Level After Cleaning (µg/cm ²)	Soil Removal
2206-408 ⁽¹⁾	PriMed Inst. 9292 SuperDART®	Double End w/Squeegee	46-0028-00 2.8mm x 73"	0.056	99.997%
	PriMed Inst. 9292 SuperDART®	Double End w/Squeegee	46-0042-00 4.2mm x 73"	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 9292 is effective in cleaning the endoscope channels with inner diameter size of 2.8mm – 4.2mm and up to 73 inches (1854mm) in length in **ONE (1) PASS** through the channel.

NOTE:

^A Study No. 2206-408 was conducted using worn channels to more accurately simulate real world conditions. The worn channels were previously exposed to one-thousand (1000) biopsy forceps insertions in order to recreate micro scratches that always present in endoscopes' channels. A scratched channel will retained more contaminants and presents a more challenging condition for the validation of the brush efficacy when compared to an unused channel.

Date of Declaration: Aug 23, 2022
Declared at: MISSISSAUGA, ONTARIO, CANADA

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Authorized By (Signature):

Authorized By (Print):

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References:

¹ Highpower Validation Testing & Lab Services Study No. 2206-408 Protocol and Final Report titled "Manual Cleaning Validation of Worn GI Endoscope Channels when using the PriMed Instruments 9292 SuperDART® Brush Protein Analysis." Cleaning efficacy validation of 9292 was completed on Aug. 5, 2022.

² 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.

SuperDART® is a registered trademark of PriMed Instruments Inc.