

Declaration of Product Performance Effectiveness

Product Family: Disposable Channel Cleaning Brush (DCCB)

Product Model: 9253 aka 9291⁽³⁾, 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⁽²⁾ 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 6.4 μ g/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 6.4 μ g/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 (μ g/cm ²)	Soil Removal
2210-652 ⁽¹⁾	PriMed Inst. 9291 SuperDART®	Double Nylon Heads w/Squeegee	46-0028-00 2.8mm x 73"	0.012	99.9994%
	PriMed Inst. 9291 SuperDART®	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 0.5 μ g/mL.

The positive sample control was greater than or equal to the assay quantitation limit of 0.5 μ g/mL.

Based on the above results we declare that the SuperDART® Product Model 9253 aka 9291⁽³⁾ 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:

^A 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):



Page 1 of 2
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):



References:

¹ 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.

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.

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

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Page 2 of 2
Initial: JK