



Medical Devices Directorate
11 Holland Avenue
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January 21, 2021

Authorization No.: 314373
Licence No.: 79049

TERESA BOYCE
DIRECTOR OF REGULATORY AFFAIRS
SCICAN LTD.
1440 DON MILLS ROAD,
TORONTO, ON, M3B 3P9
tboyce@scican.com

Re: Expanded Use Authorization

Dear TERESA BOYCE:

This letter is in reference to your request for an expansion of the licenced indications for use for certain **BRAVO AUTOCLAVES**, currently authorized for sale under Medical Device Licence number 79049, submitted in accordance with the Interim Order Respecting the Importation and Sale of Medical Devices in relation to COVID-19.

The information provided has been reviewed and meets the conditions required by section 13 of the Interim Order to include the subject device on the [List of Medical Devices for Expanded Use](#).

The new indications for expanded use are as follows:

To provide decontamination solutions for compatible N95 respirators during the SARS-CoV-2 coronavirus pandemic.

This expanded use allows for the emergency use of the BRAVO 17V or 21V Porous Wrapped 121°C Cycle in decontaminating compatible N95 flat-fold style respirators (3M 1870+, 9210+ models only, for single-user reuse by healthcare personnel.

Please note that the new indications for expanded use are limited to the BRAVO AUTOCLAVE models indicated below, with the following device identifiers:

Device name	Device identifier
BRAVO 17V AUTOCLAVE	M7A310011
	M7A310011-R
	M7A310012
	M7A310013
	M7A310013-L
	M7A310013-R
	M7A310014
	M7A310014-L
	M7A310014-R
BRAVO 21V AUTOCLAVE	M7A320011
	M7A320011-R
	M7A320012
	M7A320012-L
	M7A320012-R
	M7A320013
	M7A320013-L
	M7A320013-R
	M7A320014
M7A320014-L	
M7A320014-R	

If you have questions or require clarification, please do not hesitate to contact me directly.

Sincerely,

David Boudreau, ing.
Director General
Medical Devices Directorate
Health Products and Food Branch
Health Canada

DB/bc

cc: A. Nguyen, ROEB
B. Dowling, MDD