Provisional Authorisation for Decontamination Medical Devices

Date of provisional authorisation	22/06/2020
Applicant	STERIS Solutions Pte. Ltd.
Product owner	STERIS Corporation
Name of device	Steris V-PRO 1 Plus, V-PRO maX and V-PRO maX2 (Non-lumen cycle)
Intended purpose	For the decontamination of *compatible** N95 or FFP2 respirators for ***single user reuse*** by healthcare personnel. **Compatible* respirators here refer to respirators that does not contain cellulose based material. ***Single user reuse*** means the decontaminated mask should be returned to the same user for reuse.
Validated Parameters	
Maximum no. of decontamination cycles (per respirator)	10
Maximum no. of respirators per cycle	10 respirators individually pouched (with a maximum of 5 per shelf). Type of pouch: Tyvek pouch of at least 20cm by 30cm, identified for use in vaporized hydrogen peroxide, such as 25cm x 70m Tyvek Reels (NWTY2570). Cellulose-based pouches should not be used.
Sterilant (%)	59% Vaprox HC hydrogen peroxide sterilant (PB007, PB028, PB011 and PB012). PB007 and PB028 are only for V-PRO 1 Plus and V-PRO maX system.
Chemical indicators	VERIFY HPI chemical indicator, PCC062