

Provisional Authorisation for Decontamination Medical Devices

Date of provisional authorisation 23/06/2020

Applicant ASP Singapura Pte Ltd

Product owner Advanced Sterilization Products

Name of device ASP STERRAD 100S, NX, and 100NX Sterilization Systems

Intended purpose For the decontamination of *compatible** N95 respirators for **single user reuse** by healthcare personnel.

**Compatible* respirators here refer to respirators that do not contain cellulose based material.

Single user reuse means the decontaminated mask should be returned to the same user for reuse.

Validated Parameters

Programme Cycles 100S (Short cycle)
NX (Standard cycle)
100NX (Express cycle)

Aeration 1 hour

Maximum no. of decontamination cycles (per respirator) 2

Maximum no. of respirators per cycle 10 respirators individually pouched per load

Type of pouch:

Tyvek Self-Seal Pouches with STERRAD Chemical Indicator (12320, 12326, 12335, 12332, 12342, 12340, 12348, 12356)

Tyvek Heat-Seal Pouches with STERRAD Chemical Indicator (12521, 12526, 12532, 12541, 12548, 12543, 12544, 12557, 12558, 12559, 12560)

Cellulose-based pouches should not be used

Sterilant (%) 59% Hydrogen Peroxide
STERRAD 100NX Cassette (10144)
STERRAD NX Cassette (10133)
STERRAD 100S Cassette (10113)

Chemical indicators/ Biological indicators STERRAD Cyclesure 24 Biological Indicator (14324)
STERRAD Velocity Biological Indicator (43210)
STERRAD Chemical Indicator Strip (14100)
STERRAD Sealsure Chemical Indicator Tape (14202)