Provisional Authorisation for Decontamination Medical Devices

| **Date of provisional authorisation** | 23/06/2020 |
| **Applicant** | Johnson & Johnson 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) |