



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

<b>Record Summary</b>	463988 Steri-7 Pty Ltd - Medical device disinfectant
<b>Sponsor</b>	Steri-7 Pty Ltd
<b>Therapeutic Type</b>	Medical Device
<b>Product Category</b>	Included Class IIb
<b>ARTG Start Date</b>	9/10/2024
<b>Postal Address</b>	PO Box 22, Forestville, NSW, 2087 Australia
<b>Billing Address</b>	PO Box 22, Forestville, NSW, 2087 Australia
<b>Product Type</b>	Medical Device - Class IIb - Included
<b>Status</b>	Active
<b>Approval Area</b>	Medical Devices

**Conditions**

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.  
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

**Manufacturers**

Name	Address	Certificate number(s)
Steri-7 Pty Ltd	20/8 Tilley Lane Frenchs Forest , NSW , 2086 Australia	DV-2024-MC-29390-1

**Products**

**1 . Medical device disinfectant**

<b>Product Type</b>	Single Device Product	<b>Status</b>	Current
		<b>Effective Date</b>	9/10/2024

**GMDN** 47631 Medical device disinfectant  
**Functional Description** Not included on record  
**Intended Purpose** S-7XTRA is a cleaner/disinfectant for non-invasive medical devices and environmental surfaces. S-7XTRA Wipes are effective against bacteria, viruses including COVID-19 and MVA, fungi, and yeast. S-7XTRA Concentrate and Ready To Use solutions are also effective against b. subtilis. S-7XTRA Concentrate, RTU and Wipes when used on environmental surfaces are effective against bacteria, enveloped and non-enveloped viruses including COVID-19, Norovirus, MVA, Adenovirus, fungi (mould), yeast, mycobacteria including TB, and spores including c. difficile and b. subtilis. S-7XTRA has residual activity against SARS-CoV-2 (COVID-19), bacteria, and yeast for up to 24 hours, and biostatic activity for up to 72 hours for SARS-CoV-2 (COVID-19) and bacteria on environmental surfaces.

**Variant Information**

**Device Information**

10	Single-use devices
03	Dental devices
05	Hospital hardware

**Specific Conditions**

No Specific Conditions included on Record

Record Summary