

Examples of terminally sterilized products and the selected sterility assurance level

Sterility assurance levels for terminally sterilized products\*

<b>10<sup>-3</sup> SAL</b>	<b>10<sup>-6</sup> SAL</b> (or SAL providing greater assurance of sterility, e.g., 10 <sup>-7</sup> , 10 <sup>-8</sup> )
<p>1. Products not intended to come into contact with breached skin or compromised tissue, such as:</p> <ul style="list-style-type: none"> <li>• Collection or transfer devices:               <ul style="list-style-type: none"> <li>• Blood collection tubes for in vitro diagnostic tests</li> <li>• Culture media devices</li> <li>• Serological pipettes</li> <li>• Specimen containers</li> </ul> </li> <li>• Topical devices:               <ul style="list-style-type: none"> <li>• ECG electrodes</li> <li>• Drainage bags</li> <li>• Grounding pads</li> <li>• Surgical drapes and gowns</li> </ul> </li> <li>• Mucosal containing devices:               <ul style="list-style-type: none"> <li>• Tongue depressors</li> <li>• Examination gloves</li> <li>• Urinary catheters</li> </ul> </li> </ul> <p>2. Products that cannot withstand a 10<sup>-6</sup> SAL process:</p> <ul style="list-style-type: none"> <li>• Porcine heart valves</li> <li>• Wound dressings of a biological nature</li> </ul>	<p>1. Products intended to come into contact with breached skin or compromised tissue, such as:</p> <ul style="list-style-type: none"> <li>• Wound dressings</li> <li>• Cardiac catheters               <ul style="list-style-type: none"> <li>• Cauterizing devices</li> <li>• Scalpels and other surgical instruments</li> <li>• Surgeon's gloves</li> <li>• Syringes</li> <li>• Hypodermic needles</li> <li>• Parenteral solutions</li> <li>• Peritoneal dialysis solutions</li> </ul> </li> <li>• Prefilled syringes</li> <li>• Laparotomy sponges</li> <li>• Incise drapes</li> </ul> <p>2. Invasive products that enter normally sterile tissue</p> <p>3. Products with claims of sterile fluid pathways:</p> <ul style="list-style-type: none"> <li>• Fluid pathways of IV sets</li> <li>• Fluid pathways of syringes</li> <li>• Blood collection containers or bags</li> </ul> <p>4. Surgically implanted devices:</p> <ul style="list-style-type: none"> <li>• Reconstructive devices (e.g., hip, knee, elbow)</li> <li>• Implantable device (e.g., pacemaker)</li> <li>• Trauma devices (e.g., nails, screws, plates, pins, wires)</li> <li>• Sutures</li> <li>• Intraocular lenses</li> </ul> <p>5. Components used in aseptic processing</p>

\* Depending on its intended use and material composition, the same product may be listed in both columns and require different SALs