

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Surgical implants - Active implantable medical devices - Part 5:
Circulatory support devices
(English Translation)**

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What this standard covers

This standard specifies the basic requirements for type testing, animal experimental research and clinical evaluation of active implantable circulatory support devices. This standard applies to active implantable circulatory support devices such as left ventricular assist devices, right ventricular assist devices, total artificial hearts, biventricular assist devices, percutaneous assist devices, and pediatric assist devices. This standard also applies to some non-implanted components and accessories of active implantable circulatory support devices. This standard does not apply to routine inspections during production.

Document data

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