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<th>Identity of Specific Documents</th>
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**Chapter 1   General Requirements**

**Article 1**
- MHLW Ministerial Ordinance No. 169 dated December 17, 2004
- JIS T 14971:

**Article 2**
- JIS T 14971:

**Article 3**
- MHLW Ministerial Ordinance No. 169 dated December 17, 2004

**Article 4**
- MHLW Ministerial Ordinance No. 169 dated December 17, 2004
- JIS T 14971:

**Article 5**
- MHLW Ministerial Ordinance No. 169 dated December 17, 2004
- JIS T 14971:

**Article 6**
- JIS T 14971:

**Equivalence to existing equipment shall be evaluated for the following items.**

1. JIS T 3262:2007  Introducer needles and introducer catheters
   - 5.4.2.1 Fitting
   - 5.4.2.2 Joining strength of needle tube and needle hub
   - 5.5.2 Fracture strength
   - 5.5.3 Catheter hub
2. Port patency
3. JIS T 3210:2005  Sterile injection syringes
   - 13.2 Pressure test
   - 13.3 Suction test
4. Watertightness

**Chapter 2   Requirements for design and manufacture**

**Article 7**
- JIS T 14971:; JIS T 0993-1:
- JIS T 14971:; JIS T 0993-1:
- JIS T 14971:
- JIS T 14971:; JIS T 0993-1:
- JIS T 14971:

**Article 8**
- MHLW Ministerial Ordinance No. 169 dated December 17, 2004
- Not applied
- MHLW Ministerial Ordinance No. 169 dated December 17, 2004
- Not applied
- Not applied
- Not applied
- Not applied
- Partially applied PFSB/CND Notification No. 0330001 dated March 30, 2005
- Partially applied PFSB/CND Notification No. 0330001 dated March 30, 2005
- Partially applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004
- Partially applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004
- Partially applied JIS T 14971:; PFSB Notification No. 0310003 dated March 10, 2005
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