### Chapter 1   General Requirements

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

**Article 2** Applied
- JIS T 14971:

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

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

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

**Article 6** Applied
- JIS T 14971:

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

1) Securing the tube lumen
2) Connectivity with connectors
3) Cuff airtightness
4) Connectivity of inflating tube
5) Compatibility of assembly part of components

### Chapter 2   Requirements for design and manufacture

**Article 7**

1. Applied
   - JIS T 14971:
   - JIS T 0993-1:
2. Applied
   - JIS T 14971:
   - JIS T 0993-1:
3. Applied
   - JIS T 14971:
4. Not applied
5. Applied
   - JIS T 14971:
6. Applied
   - JIS T 14971:

**Article 8**

1. Applied
   - MHLW Ministerial Ordinance No. 169 dated December 17, 2004
2. Not applied
3. Applied
   - MHLW Ministerial Ordinance No. 169 dated December 17, 2004
   - Not applied
   - Not applied
   - Not applied
   - Not applied
   - Not applied
   - Applied
   - PFSB/CND Notification No. 0330001 dated March 30, 2005
   - Applied
   - PFSB/CND Notification No. 0330003 dated March 10, 2005
4. Not applied
5. Not applied
6. Applied
   - JIS T 14971:

**Article 9**

1. Applied
   - JIS T 14971:

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**Essential Principles in Japan Version 2005**

**Applied / Not applied**

**Identity of Specific Documents**
<table>
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Applied