### Essential Principles Checklist (Sterilizer, gas, formaldehyde)

#### 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:

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

1. Operating pressure range
2. Vacuum tolerance of sterilization chamber
3. Operation temperature of sterilization chamber
4. Processing performance; sterility assurance level (SAL)
5. Residual formaldehyde concentration after sterilization process

#### Chapter 2   Requirements for design and manufacture

**Article 7**

1. Applied
   - JIS T 14971:
   - JIS C 1010-1:2005

2. Not applied

3. Applied
   - JIS T 14971:

2. Not applied

3. First Applied
   - JIS T 14971:

4. Not applied

5. Applied
   - JIS T 14971:
   - EN 14180:2003

**Article 8**

1. Not applied

2. Not applied

3. Not applied

4. Not applied

5. Not applied

6. Not applied

7. Not applied

8. Not applied

9. Not applied

10. Not applied

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**Partially applied**

- JIS T 14971:
- PFSB Notification No. 0310003 dated March 10, 2005

**Article 9**

1. Applied
   - JIS T 14971:
   - JIS C 1010-1:2005

2. Applied
   - JIS T 14971:

3. Applied
   - JIS T 14971:

4. Applied
   - JIS T 14971:
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PFSB Notification No. 031003 dated March 10, 2005:

JIS T 14971:

JIS C 1010-1:2005

PFSB Notification No. 0331032 dated March 31, 2005

Applied