### Essential Principles Checklist (Reservoir, cerebrospinal fluid)

**Chapter 1  General Requirements**

- **Article 1** Applied
- **Article 2** Applied
- **Article 3** Applied
- **Article 4** Applied
- **Article 5** Applied
- **Article 6** Applied

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

1. Valve opening pressure
2. Stopcock leakage
3. Storage tank leakage
4. Compatibility of connection part with other medical devices

**Chapter 2  Requirements for design and manufacture**

- **Article 7**
  1. Applied
  2. Applied
  3. Applied
  4. Not applied
  5. Applied
  6. Applied

- **Article 8**
  1. Applied
  2. Not applied
  3. Applied
  4. Not applied
  5. Not applied
  6. Applied
  7. Applied
  8. Applied
  9. Not applied
  10. Not applied
  11. Applied

Applied JIS T 14971; PFSB Notification No. 0310003 dated March 10, 2005

- **Article 9**
  1. Applied
  2. Applied
  3. Applied
  4. Applied
  5. Not applied

Applied JIS T 14971; PFSB Notification No. 0310003

---

*Note: The table contains detailed specifications and guidelines for the application of essential principles in Japan.*
<table>
<thead>
<tr>
<th>Article</th>
<th>Applied</th>
<th>JIS T 14971: Not applied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 101</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>Article 111</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>Article 121</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>Article 131</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>Article 14</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>Article 15</td>
<td>Not applied</td>
<td></td>
</tr>
</tbody>
</table>

Applied PFSB Notification No. 0310032 dated March 31, 2005; JIS T 14971: Not applied

Applied PFSB Notification No. 0310032 dated March 31, 2005; JIS T 14971: Not applied