### Essential Principles Checklist (Adaptor, catheter, intravenous)

<table>
<thead>
<tr>
<th>Article</th>
<th>Applied</th>
<th>Not applied</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>JIS T 3212:2005 Sterile blood transfusion set</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Connection strength of connection part</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>JIS T 14971:</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>JIS T 14971:</td>
<td></td>
</tr>
</tbody>
</table>

### Requirements for design and manufacture

<table>
<thead>
<tr>
<th>Article</th>
<th>Applied</th>
<th>Not applied</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>JIS T 14971:</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>JIS T 0993-1:</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>JIS T 14971:</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Additional notes

- Equivalence to existing equipment shall be evaluated for the following items:
  - JIS T 3212:2005 Sterile blood transfusion set
  - JIS T 14971: Airtightness
  - Coinjection part
  - Connection strength of connection part

- 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:; JIS T 0993-1:
    - 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
    - 4 Not applied
    - 5 Not applied
    - 6 Partially applied PFSB/CND Notification No. 0330001 dated March 30, 2005
    - 7 Partially applied PFSB/CND Notification No. 0330001 dated March 30, 2005
    - 8 Partially applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004
    - 9 Partially applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004
    - 10 Partially applied JIS T 14971: Applied JIS T 14971:; PFSB Notification No. 0310003 dated March 10, 2005
  - Article 9
    - 1 Applied JIS T 14971:
    - 2 Applied JIS T 14971:
    - 3 Applied JIS T 14971:
    - 4 Applied JIS T 14971:
    - 5 Not applied