### Essential Principles Checklist (Cannula, Arthroscopy drainage)

<table>
<thead>
<tr>
<th>Essential Principles</th>
<th>Cannula, Arthroscopy drainage</th>
</tr>
</thead>
</table>

**Chapter 1   General Requirements**

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

**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. **Catheter**
   - (1) Clogging and leakage during injection or suction
   - (2) Tensile strength of joining part
   - (3) Compatibility of connection part with connection tube

2. **Trocar, obturator**
   - (1) Tensile strength
   - (2) Tensile strength of joining part

3. **Connection tube**
   - (1) Pressure resistance at suction

**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

- 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:

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

**Article 9**
- 1 Partially applied
  - JIS T 14971:

- 2 Partially applied
  - PFSB/CND Notification No. 0330001 dated March 30, 2005

- 3 Partially applied
  - MHLW Ministerial Ordinance No. 169 dated December 17, 2004

- 4 Partially applied
  - MHLW Ministerial Ordinance No. 169 dated December 17, 2004

- 5 Partially applied
  - JIS T 14971:

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

- 6 Not applied
<table>
<thead>
<tr>
<th>Article</th>
<th>Applied JIS T 14971</th>
<th>Applied PFSB Notification No. 0310003 dated March 31, 2005</th>
<th>JIS T 14971:</th>
</tr>
</thead>
<tbody>
<tr>
<td>101</td>
<td>Not applied</td>
<td></td>
<td></td>
</tr>
<tr>
<td>111</td>
<td>Not applied</td>
<td></td>
<td></td>
</tr>
<tr>
<td>121</td>
<td>Not applied</td>
<td></td>
<td></td>
</tr>
<tr>
<td>131</td>
<td>Not applied</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Not applied</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Not applied</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Applied PFSB Notification No. 0310003 dated March 31, 2005; JIS T 14971