<table>
<thead>
<tr>
<th>Identity of Specific Documents</th>
<th>Essential Principles in Japan</th>
<th>Version 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter 1  General Requirements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Article 1  Applied</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:</td>
<td></td>
</tr>
<tr>
<td>Article 2  Applied</td>
<td>JIS T 14971:</td>
<td></td>
</tr>
<tr>
<td>Article 3  Applied</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004</td>
<td></td>
</tr>
<tr>
<td>Article 4  Applied</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:</td>
<td></td>
</tr>
<tr>
<td>Article 5  Applied</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:</td>
<td></td>
</tr>
<tr>
<td>Article 6  Applied</td>
<td>JIS T 14971:</td>
<td></td>
</tr>
</tbody>
</table>

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

1) Bond strength of anastomotic rings

Chapter 2  Requirements for design and manufacture

| Article 7 1 Applied | JIS T 14971:; JIS T 0993-1: |              |
| Article 2  Applied | JIS T 14971:; JIS T 0993-1: |              |
| Article 3  Applied | JIS T 14971: |              |
| Article 4  secondNot applied | |              |
| Article 5  Applied | JIS T 14971:; JIS T 0993-1: |              |
| Article 6  Applied | JIS T 14971: |              |

Article 8 1 Applied

1) MHLW Ministerial Ordinance No. 169 dated December 17, 2004
2) Not applied
3) Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004
2) Not applied
3) Not applied
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 Applied

1) JIS T 14971:
2) Applied JIS T 14971:
3) Applied JIS T 14971:
4) Applied JIS T 14971:
5) Not applied
6) Not applied
7) Not applied
8) Not applied
9) Not applied
10) Not applied

2 Not applied
<table>
<thead>
<tr>
<th>1</th>
<th>Article101 Not applied</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Not applied</td>
</tr>
<tr>
<td>3</td>
<td>Not applied</td>
</tr>
<tr>
<td>4</td>
<td>Not applied</td>
</tr>
<tr>
<td>5</td>
<td>Not applied</td>
</tr>
<tr>
<td>6</td>
<td>Not applied</td>
</tr>
<tr>
<td>7</td>
<td>Not applied</td>
</tr>
<tr>
<td>8</td>
<td>Not applied</td>
</tr>
<tr>
<td>9</td>
<td>Article111 Not applied</td>
</tr>
<tr>
<td>10</td>
<td>Not applied</td>
</tr>
<tr>
<td>11</td>
<td>Not applied</td>
</tr>
<tr>
<td>12</td>
<td>Not applied</td>
</tr>
<tr>
<td>13</td>
<td>Not applied</td>
</tr>
<tr>
<td>14</td>
<td>Article121 Not applied</td>
</tr>
<tr>
<td>15</td>
<td>Not applied</td>
</tr>
<tr>
<td>16</td>
<td>Not applied</td>
</tr>
<tr>
<td>17</td>
<td>Not applied</td>
</tr>
<tr>
<td>18</td>
<td>Not applied</td>
</tr>
<tr>
<td>19</td>
<td>Applied</td>
</tr>
</tbody>
</table>

- PFSB Notification No. 0310003 dated March 10, 2005; JIS T 14971:
- Article161 Applied
- PFSB Notification No. 0331032 dated March 31, 2005
- Not applied