Ministerial Notification No. 112, Appendix Table, No.3-454
Essential Principles Checklist (Curette, ophthalmic, single-use)

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

Chapter 2 Requirements for design and manufacture

| 1 | Partially applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004 |
| 2 | Not applied |
| 3 | Partially applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004 |
| 4 | Not applied |
| 5 | Not applied |
| 6 | Not applied |
| 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

<p>| 1 | Partially applied JIS T 14971: |
| 2 | Partially applied JIS T 14971: |
| 3 | Partially applied JIS T 14971: |
| 4 | Partially applied JIS T 14971: |
| 5 | Not applied |
| 6 | Partially applied JIS T 14971: |
| 7 | Partially applied JIS T 14971: |</p>
<table>
<thead>
<tr>
<th>Article</th>
<th>Applied</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>101</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>111</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>121</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Partially applied</td>
<td>JIS T 14971:</td>
</tr>
<tr>
<td>2</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Not applied</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Not applied</td>
<td></td>
</tr>
</tbody>
</table>

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

PFSB Notification No. 0331032 dated March 31, 2005

2 Not applied