### Essential Principles Checklist (Colour matching test material, dental)

<table>
<thead>
<tr>
<th>Article</th>
<th>Applied/Not applied</th>
<th>Identity of Specific Documents</th>
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<tr>
<td>1</td>
<td>Applied</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:</td>
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<td>2</td>
<td>Applied</td>
<td>JIS T 14971:; PFSB/ELD/OMDE Notification No. 0831002 dated August 31, 2007; JIS T 0993-1:; JIS T 6001:</td>
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<td>3</td>
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<td>PFSB/ELD/OMDE Notification No. 0831002 dated August 31, 2007</td>
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<td>4</td>
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<td>5</td>
<td>Applied</td>
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</tr>
<tr>
<td>6</td>
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## Chapter 1  General Requirements

### Article 1

- Applied
- MHLW Ministerial Ordinance No. 169 dated December 17, 2004
- JIS T 14971:

### 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:

## Chapter 2  Requirements for design and manufacture

### Article 7

1. Applied
   - JIS T 14971:
   - PFSB/ELD/OMDE Notification No. 0831002 dated August 31, 2007
   - JIS T 0993-1:
   - JIS T 6001:

2. Applied
   - JIS T 14971:
   - PFSB/ELD/OMDE Notification No. 0831002 dated August 31, 2007
   - JIS T 0993-1:
   - JIS T 6001:

3. First applied
   - JIS T 14971:

4. Not applied

5. Applied
   - JIS T 14971:

6. Applied
   - JIS T 14971:

### Article 8

1. Not applied

2. Applied
   - MHLW Ministerial Ordinance No. 169 dated December 17, 2004

3. Not applied

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

5. Not applied

6. Not applied

7. Not applied

8. Not applied

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

10. Not applied

## Chapter 3  Requirements for clinical evaluation

### Article 9

1. Not applied

2. Applied
   - JIS T 14971:

3. Not applied

4. Applied
   - JIS T 14971:
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Applied PFSB/SD Notification No. 0310004 dated March 10, 2005; JIS T 14971:

Applied PFSB Notification No. 0331032 dated March 31, 2005