Essential Principles Checklist (Laser lens, ophthalmic, surgical)

<table>
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<tr>
<th>Identity of Specific Documents</th>
<th>Essential Principles in Japan</th>
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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:

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

1) Standard of Contact Lens for Visual Acuity Correction (MHLW Ministerial Announcement No. 349 dated October 5, 2001)

Part 3  Quality

1. Shape and appearance

2. Laser light permeability

3. Radius of curvature of ocular 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. Not applied

7. Not applied

8. Not applied

9. Not applied

10. Not applied

- 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. Not applied

5. Not applied

6. Not applied

7. Not applied

8. Not applied

9. Not applied

10. Not applied

- Applied

- JIS T 14971;

- PFSB Notification No. 0310003 dated March 10, 2005
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