### Essential Principles in Japan

#### Version 2005

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<th>General Requirements</th>
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Equivalence to existing equipment shall be evaluated for the following items.
1) Puncture function of the tip part

### Chapter 2 | Requirements for design and manufacture

| Article 7 | Applied JIS T 14971:; JIS T 0993-1: |
| Article 8 | Applied JIS T 14971:; JIS T 0993-1: |
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### Article 1
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
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: Not applied

### Article 2
1. Applied 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
2. Not applied
3. Not applied
4. Not applied
5. Not applied
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### Article 3
1. Applied JIS T 14971: |
2. Applied JIS T 14971: |
3. Applied JIS T 14971: |
4. Applied JIS T 14971: |
5. Not applied
6. Not applied
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### Article 4
1. Applied 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
2. Not applied
3. Not applied
4. Not applied
5. Not applied
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7. Partially applied PFSB/CND Notification No. 0330001 dated March 30, 2005
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10. Partially applied JIS T 14971: Not applied

### Article 5
1. Applied JIS T 14971: |
2. Applied JIS T 14971: |
3. Applied JIS T 14971: |
4. Applied JIS T 14971: |
5. Not applied
6. Not applied
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### Article 6
1. Applied 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
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3. Not applied
4. Not applied
5. Not applied
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10. Partially applied JIS T 14971: Not applied

### Article 7
1. Applied 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
2. Not applied
3. Not applied
4. Not applied
5. Not applied
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10. Partially applied JIS T 14971: Not applied

### 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
2. Not applied
3. Not applied
4. Not applied
5. Not applied
6. Partially applied PFSB/CND Notification No. 0330001 dated March 30, 2005
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9. Partially applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004
10. Partially applied JIS T 14971: Not applied

### Article 9
1. Applied JIS T 14971: |
2. Applied JIS T 14971: |
3. Applied JIS T 14971: |
4. Applied JIS T 14971: |
5. Not applied
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**Notes:**
- Applied PFSB Notification No. 0310003 dated March 10, 2005; JIS T 14971.