### Essential Principles Checklist (Pulse oximeter/capnometer)

#### Chapter 1   General Requirements

1. **Article 1** Applied
   - MHLW Ministerial Ordinance No. 169 dated December 17, 2004
   - JIS T 14971:

2. **Article 2** Applied
   - JIS T 0601-1:
   - JIS T 14971:

3. **Article 3** Applied
   - MHLW Ministerial Ordinance No. 169 dated December 17, 2004

4. **Article 4** Applied
   - MHLW Ministerial Ordinance No. 169 dated December 17, 2004
   - JIS T 14971:

5. **Article 5** Applied
   - MHLW Ministerial Ordinance No. 169 dated December 17, 2004
   - JIS T 14971:

6. **Article 6** Applied
   - JIS T 14971:

#### 1. Pulse oximeter

Perform the test of probes and device by attaching a pulse oximeter tester to the optical system using the probes intended to be connected and verify the following 4 performance items.

1-1. **SpO2 measurement precision**
   - ISO 9919 Annex FF
   - SpO2 measurement precision shall be equivalent to that of existing equipment.

1-2. **Pulse rate measurement precision (applicable only to equipment with this function)**
   - ISO 9919 50.104 Pulse rate precision
   - Pulse rate measurement precision shall be equivalent to that of existing equipment.

1-3. **SpO2 alarm function (applicable only to equipment with this function)**
   - ISO 9919 104 Alarm systems
   - SpO2 alarm function shall work as set.

1-4. **Pulse rate alarm function (applicable only to equipment with this function)**
   - ISO 9919 104 Alarm systems
   - Pulse rate alarm function shall work as set.

The above tests in items 1-1 to -4 describe the way of optically connecting the pulse oximeter tester to the probe. If the probe intended to be connected and the equipment are identical, the test may be performed by directly, electrically connecting the tester to the equipment.

#### 2. Capnometer

The following items shall be stipulated when a sampling tube or sensor for carbonic acid gas measurement intended to be connected is connected to the capnograph/pulse oximeter.

2-1. **Precision**
   - Follow ISO 21647 51.101.1.

2-2. **Stability of precision**
   - Follow ISO 21647 51.101.2.

2-3. **Indicating unit**
   - Follow ISO 21647 6.3 and 51.103.
## Chapter 2   Requirements for design and manufacture

### Article 71

1. Applied JIS T 0601-1; JIS T 14971:
2. Applied JIS T 0993-1; JIS T 14971:
3. Applied JIS T 0601-1; JIS T 14971:
4. Not applied
5. Applied JIS T 14971:

### Article 81

1. Partially applied JIS T 14971; JIS T 0601-1:
2. Partially applied JIS T 14971; JIS T 0601-1:
3. Not applied
4. Not applied
5. Not applied
6. Not applied

### Article 91

1. Applied JIS T 14971:
2. Applied JIS T 0601-1; JIS T 0601-1-2:
3. Applied JIS T 14971:
4. Applied JIS T 0601-1:
5. Not applied
6. Applied JIS T 14971:

### Article 101

1. Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:
2. Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004
3. Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004
4. Applied JIS T 14971:
5. Applied JIS T 0601-1:

### Article 111

1. Not applied
2. Not applied
3. Not applied
4. Partially applied JIS T 0601-1:
5. Not applied
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