### 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) JIS T 0601-2-35:2015  Medical electrical equipment - Part 2-35:
Particular requirements for the basic safety and essential performance of
heating devices using blankets, pads or mattresses and intended for heating
in medical use

201.11.1.2.1 Maximum contact surface temperature in normal
condition

201.11.8.1 Power supply /supply mains interruption technical alarm
condition

201.12.3 Alarm systems

201.12.4.104 Accuracy of contact surface temperature

201.12.4.106 Avoidance of incorrect connection of parts

2) Setting range of body temperature

3) Setting range of water temperature

### Chapter 2   Requirements for design and manufacture

**Article 7**
1 Applied
JIS T 14971:;JIS T 0601-2-35:

2 Partially applied
JIS T 14971:;JIS T 0601-2-35:

3 Applied
JIS T 14971:;JIS T 0601-2-35:

2 Not applied

3 Partially applied
JIS T 14971:;JIS T 0601-2-35:

4 First
Partially applied
JIS T 14971:;JIS T 0601-2-35:

Second
Not applied

5 Not applied

6 Applied
JIS T 14971:;JIS T 0601-2-35:

7 Applied
JIS T 14971:;JIS T 0601-2-35:

**Article 8**
1 Applied
JIS T 14971:

2 Not applied

3 Applied
JIS T 14971:;JIS T 0601-2-35:

2 Not applied

3 Not applied

4 Not applied

5 Not applied

6 Not applied

7 Not applied
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