Essential Principles Checklist (Catheter, bronchial obstruction, ventilation)

<table>
<thead>
<tr>
<th>Article</th>
<th>Applied</th>
<th>Not applied</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) Catheter
   (1) Tensile strength of catheter
   (2) Cuff airtightness
   (3) Connectivity of inflating tube

Chapter 2   Requirements for design and manufacture

Article 7 | 1 Applied |
JIS T 14971:;JIS T 0993-1:

Article 8 | 2 Applied |
JIS T 14971:;JIS T 0993-1:

Article 9 | 3 Applied |
MHLW Ministerial Ordinance No. 169 dated December 17, 2004

Article 10 | 2 Not applied |

Article 11 | 3 Not applied |

Article 12 | 4 Not applied |

Article 13 | 5 Not applied |

Article 14 | 6 Applied |
PFSB/CND  Notification No. 0330001 dated March 30, 2005

Article 15 | 7 Applied |
PFSB/CND  Notification No. 0330001 dated March 30, 2005

Article 16 | 8 Applied |
MHLW Ministerial Ordinance No. 169 dated December 17, 2004

Article 17 | 9 Not applied |

Article 18 | 10 Not applied |

AppliedJIS T 14971;PFSB Notification No. 0310003 dated March 10, 2005

Article 19 | 1 Applied |

Article 20 | 2 Applied |

Article 21 | 3 Applied |

Article 22 | 1 Applied |

Article 23 | 2 Applied |

Article 24 | 3 Applied |

Article 25 | 1 Applied |

Article 26 | 2 Applied |

Article 27 | 3 Applied |

Article 28 | 1 Applied |

Article 29 | 2 Applied |

Article 30 | 3 Applied |

Article 31 | 1 Applied |

Article 32 | 2 Applied |

Article 33 | 3 Applied |

Article 34 | 1 Applied |

Article 35 | 2 Applied |

Article 36 | 3 Applied |

Article 37 | 1 Applied |

Article 38 | 2 Applied |

Article 39 | 3 Applied |

Article 40 | 1 Applied |

Article 41 | 2 Applied |

Article 42 | 3 Applied |

Article 43 | 1 Applied |

Article 44 | 2 Applied |

Article 45 | 3 Applied |
| 項目 | 本文 | 14971 | 証明書送付 | 証明書検査 | 証明書検査
|------|------|-------|-------------|-------------|-------------
| Article 101 | Not applied | | | |
| Article 111 | Not applied | | | |
| Article 121 | Not applied | | | |
| Article 131 | Not applied | | | |
| Article 14 | Not applied | | | |
| Article 15 | Not applied | | | |

Applied PFSB Notification No. 0310003 dated March 10, 2005; JIS T 14971: Not applied