## Essential Principles Checklist (Endotherapy cannula, single-use)

### Chapter 1   General Requirements

**Article1** Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS_T_14971:

**Article2** Applied JIS_T_14971:

**Article3** Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004

**Article4** Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS_T_14971:

**Article5** Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS_T_14971:

**Article6** Applied JIS_T_14971:

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

1. JIS T 1553:2005  Optics and optical instruments-Medical endoscopes and endotherapy devices
2. **3.12 Effective length**
3. **3.10 Maximum insertion portion width**
4. **3.11 Minimum instrument channel width**

### Chapter 2   Requirements for design and manufacture

**Article71**

1. Applied JIS_T_14971:; JIS_T_0993-1:
2. Applied JIS_T_14971:; JIS_T_0993-1:
3. Applied JIS_T_14971:
4. Partially applied JIS_T_14971:
5. Not applied
6. Applied JIS_T_14971:; JIS_T_0993-1:

**Article81**

1. Applied JIS_T_14971:
2. Not applied
3. Applied PFSB Notification No. 1002-8 dated October 2, 2014; JIS_T_14971:
4. Not applied
5. Not applied
6. Not applied
7. Not applied
8. Not applied

**Article91** Partially applied JIS_T_14971:

2. Partially applied JIS_T_14971:; PFSB Notification No. 1002-8 dated October 2, 2014
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