### Essential Principles Checklist (Suction system, dental etc)

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<th>Identity of Specific Documents</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:

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### Dental suction equipment

**JIS T 5801:2016  Dental equipment  Suction systems**

5.3 Requirements on performance

5.4 Requirements for accessories

5.6 Noise

- **Dimensions of the connection part** (for products without suction pump)
  
  The marketing authorization holder shall specify the dental suction equipment pump that can be used for the product. Using the specified dental suction equipment pump as the suction source, the equipment shall conform to performance items as specified in JIS T 5801.

- **(for the dental suction equipment with a steam separator)**
  
  Check that the steam separator has a structure which separates water from air, and prevents water from flowing into the suction pump by the following.

  **Checking methods:**
  
  (i) The equipment shall have a mechanism to prevent liquid from entering the suction pump by way of a short circuit where the liquid was sucked into the steam separator but not separated.

  (ii) When suction is performed until fully filled with water, "Water level sensor to control the suction pump shall be activated."

  **or**

  "The structure shall have a mechanism to close the flow line of suction pump of the steam separator."

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**Dental suction equipment pump**

**JIS T 5801:2016  Dental equipment  Suction systems**

5.3 Requirements on performance

Dental suction equipment pump shall conform to the performance items above under the conditions designated by marketing authorization holders.

(for the dental suction equipment pump with steam separator)

Check that the steam separator has a structure which separates water from air, and prevents water from flowing into the suction pump by the following.

**Checking methods:**

(i) The equipment shall have a mechanism to prevent liquid from entering the suction pump by way of a short circuit where the liquid was sucked into the steam separator but not separated.
(ii) When suction is performed until fully filled with water, "Water level sensor to control the suction pump shall be activated."

Chapter 2   Requirements for design and manufacture

**Article 71**

1. Applied JIS_T_5801:2016; JIS_T_14971;
2. PFSB/ELD/OMDE Notification No. 0301-1 dated March 1, 2012

**Article 81**

1. Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004
2. Applied JIS_T_14971:
3. Applied MHLW Ministerial Ordinance No. 169 dated December 17, 2004
2. Not applied
3. Not applied
4. Not applied
5. Not applied
6. Not applied
7. Not applied
8. Not applied
9. Applied JIS_T_14971; MHLW Ministerial Ordinance No. 169 dated December 17, 2004
10. Not applied

**Article 91**

1. Applied JIS_T_14971; JIS_T_5801:2016; JIS_T_14971:
2. Applied PFSB Notification No. 1002-8 dated October 2, 2014; JIS_T_14971:
4. Partially applied JIS_T_14971; JIS_T_5801:2016
5. Applied JIS_T_14971; JIS_T_5801:2016
7. Not applied
9. Applied JIS_T_14971:
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