### Essential Principles Checklist (Handpiece, endodontic, multi-purpose, powered)

#### 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:

#### Partial revision of the Basic Principles of Electrical Safety Evaluation and Physical/Chemical Evaluation Required for Application for Approval to Market Dental Equipment

PFSB/ELD/OMDE Notification No. 0131-6 dated Jan 31, 2014

1) Shape

2) Dimensions

3) Surface condition

4) Shock resistance

5) Static transmission force

6) Rotation control function

7) Rotation speed

8) Rotation direction

9) Eccentricity

10) Air amount for motor cooling

11) Air pressure for motor cooling

12) Measurement precision of root canal length

13) Indication precision of root canal length

14) Spray ability

15) No-load rotation speed

#### Chapter 2   Requirements for design and manufacture

**Article 71**

1 Applied JIS T 14971; PFSB/ELD/OMDE Notification No. 0301-1 dated March 1, 2012; JIS T 0601-1:2014

2 Applied JIS T 14971; PFSB/ELD/OMDE Notification No. 0301-1 dated March 1, 2012; JIS T 0601-1:2014


2 Not applied

3 Applied JIS T 14971; PFSB/ELD/OMDE Notification No. 0301-1 dated March 1, 2012; JIS T 0601-1:2014

4 first Applied JIS T 14971: second Not applied

5 Not applied

6 Applied JIS T 14971; PFSB/ELD/OMDE Notification No. 0301-1 dated March 1, 2012

7 Applied JIS T 14971; JIS T 0601-1:2014

**Article 81**

July 27, 2017

July 27, 2017
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*July 27, 2017*
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