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Acupuncture needle for single use

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Industries Association of Physical Therapy Device (JIPT)/Japanese Standards Association (JSA), with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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Acupuncture needle for single use

1 Scope This Japanese Industrial Standard specifies requirements for acupuncture needles for single use (hereafter referred to as “acupuncture needles”) used for acupuncture treatment, which are disposed after single use. However, the acupuncture needle has two types: a sterile needle, ready to use, with indication that it has been sterilized in the manufacturing process, and an unsterilized needle.

2 Normative references The following standards contain provisions which, through reference in the text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS C 2502 *Materials for permanent magnet*

JIS G 3521 *Hard drawn steel wires*

JIS G 4308 *Stainless steel wire rods*

JIS G 4309 *Stainless steel wires*

JIS G 4314 *Stainless steel wires for springs*

JIS H 3270 *Copper beryllium alloy, Phosphor bronze and nickel silver rods, bars and wires*

JIS H 8620 *Electroplated coatings of gold and gold alloy for engineering purposes*

JIS H 8622 *Electroplated coatings of gold and gold alloy for decorative purposes*

JIS T 6101 *Nickel-chromium alloy wires for dental use*

JIS T 6104 *Cobalt-chromium alloy wires for dental use*

3 Terms and definitions For the purposes of this Standard, the following definitions apply.

- a) **nominal diameter of wire** dimension of diameter of wire of the needle body marked on the encapsulation or the container of acupuncture needle
- b) **nominal length** dimension of length of the needle body marked on the encapsulation or the container of acupuncture needle
- c) **needle body** part of acupuncture needle to be inserted into the human body
- d) **water** “purified water” specified in Japanese Pharmacopoeia, Part II, Official Monographs, or water with the equivalent or higher property
- e) **water for endotoxin test** “water for injection” specified in Japanese Pharmacopoeia, Part II, Official Monographs or water prepared by the other method not responsive to the detection limit of Lysate (LAL) reagent used for endotoxin test
- f) **sterilized needle** acupuncture needle with indication that it has been sterilized in the manufacturing process, which is ready to use
- g) **unsterilized needle** acupuncture needle which is not sterilized in the manufacturing process and not allowed to indicate as sterilized