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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 4234.1-2026

Implants for surgery - Metallic materials - Part 1: Wrought stainless steel

外科植入物 金属材料 第1部分：锻造不锈钢

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Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020 Directives for standardization - Part

1.Rules for the structure and drafting of standardizing documents. This document is Part 1 of GB 4234 Implants for surgery - Metallic materials. GB 4234 has already published the following parts. -- Part

1 Scope

GB 4234.1 is the mandatory Chinese standard for the wrought stainless steel used to make surgical implants, and it is Part 1 of the series on implant metals. It specifies what the material has to be before anything is machined from it: the chemical composition, the microstructure, the mechanical properties, the corrosion resistance and the test methods that verify them. Stainless steel remains the workhorse of trauma surgery, used for plates, screws, nails and wires that carry load inside the body for months or years, and an implant is only ever as good as the bar or sheet it was cut from: an inclusion or a wrong heat treatment produces a device that fails in service with no warning. Being a GB standard without the /T suffix, compliance is compulsory in China. It takes effect in May 2029, which is the date a manufacturer or a mill supplying the Chinese market has to work back from.

This document specifies the performance requirements for wrought stainless steel used in surgical implants and describes the corresponding test methods. This document applies to the testing and evaluation of wrought stainless steel materials used in surgical implants. NOTE. The alloys described in this document correspond to alloys with UNS number

S31673 in ASTM F138/ASTM F139.

2 Normative references

The provisions of the following documents constitute the essential clauses of this document through normative references in this text. Among them, for any dated reference, only the version corresponding to that date applies to this document; for any undated reference, the latest version (including all amendments) applies to this document.

GB/T 223(all parts) Iron, steel and alloy

GB/T 228.1-2021 Metallic materials - Tensile testing - Part

3 Terms and definitions

For the purposes of this document, the terms and definitions given in GB/T 228.1-2021 apply.

4 Chemical composition

4.1 Specimen The selection of specimens for analysis shall comply with the provisions of GB/T 2975.

11 Wrought titanium 6-aluminium 7-niobium alloy; -- Part

12.Wrought cobalt-chromium-molybdenum alloy. This document replaces GB 4234.1-2017 Implants for surgery - Metallic materials - Part

1.Wrought stainless steel. Compared with GB 4234.1-2017, apart from structural adjustments and editorial changes, the main technical changes are as follows: -- The chapter "Terms and definitions" has been added (see Chapter 3); -- The requirements for silicon (Si) in the chemical composition have been changed, and the requirements for cobalt (Co) have been added (see Table 1; see Table 1 in the 2017 edition); -- The requirements for the mechanical properties of the wire have been changed (see Table 4; see Table 4 in the 2017 edition); -- The requirements for gauge length of mechanical properties have been changed (see 6.3; see

5.3 in the 2017 edition); -- The test methods for carbon (C), silicon (Si), manganese (Mn), sulfur (S), and phosphorus (P) have been changed (see Table 6; see Table 6 in the 2017 edition). Implants for surgery - Metallic materials - Part