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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 43277.2-2023

**Clamps and flow regulators for medical infusion and
transfusion equipment - Part 2: Graduated flow regulators with
fluid contact**

医用输液（输血）器具用止流夹和流量调节器 第2部分：液体接触式刻度流量调
节器

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents" Drafting:

This document is Part 2 of GB/T 43277 "Clamps and flow regulators for medical infusion (blood transfusion) equipment": GB/T 43277 the following sections have been published:

---Part 1: Non-liquid contact stop clamps and flow regulators;

---Part 2: Liquid contact scale flow regulator:

This document is modified to adopt ISO 8536-13:2016 "Medical infusion equipment - Part 13: Liquid contact disposable scale flow rate" Regulator":

Compared with ISO 8536-13:2016, this document has made the following structural adjustments:

---6:5:1 and 6:5:2 correspond to 6:5 in ISO 8536-13:2016;

---Appendix B corresponds to A:4 in the ISO 8536-13:2016 appendix:

The technical differences between this document and ISO 8536-13:2016 and their reasons are as follows:

---Replaced ISO 8536-4 with GB 8368 (see Chapter 7 and Chapter 8) for ease of use;

---Replaced ISO 10993-1 (see Chapter 5) with GB/T 16886.1 for ease of use;

---Added normative appendix B, supplemented the test content on flow rate in A:4 of ISO 8536-13:2016, and added instrument instruments, test procedures and calculation formulas to increase the operability of the standard:

The following editorial changes have been made to this document:

---In order to coordinate with my country's technical standard system, the standard name is

changed to "Clamps and Flow Regulators for Medical Infusion (Blood Transfusion) Apparatus" Part 2: Liquid Contact Scale Flow Regulators";

---Added notes to 6:5:1 and Chapter 7:

Please note that some content in this document may be subject to patents: The publisher of this document assumes no responsibility for identifying patents:

Introduction

Flow-stop clamps and flow regulators for medical infusion (blood transfusion) equipment, also known as pipe clamps, flow-stop clamps, hose flow adjustment clamps, etc., are used as infusion sets Product components of the equipment, usually assembled into the pipeline part of the infusion equipment, are used to regulate and control the flow of liquid in the pipeline: Divided into liquid contacts There are two categories: contact with liquid and non-contact with liquid:

GB/T 43277 "Clamps and flow regulators for medical infusion (blood transfusion) equipment" is a component product standard: GB/T 43277 is intended to regulate Determines the performance requirements for stop clamps and flow regulators used in medical infusion (blood transfusion) equipment, and is intended to consist of two parts:

---Part 1: Non-liquid contact stop clamps and flow regulators: The purpose is to specify non-liquid contact stop clamps and flow regulators:

Controller performance requirements:

---Part 2: Liquid contact scale flow regulator: The purpose is to specify performance requirements for liquid contact graduated flow regulators:

Flow-stop clamps and flow regulators for medical infusion (blood transfusion) equipment
Part 2: Liquid Contact Scale Flow Regulators

1 Scope

This document specifies the design, materials, physical requirements, and chemical requirements of liquid contact scale flow regulators for medical infusion and blood transfusion equipment:

and biological requirements:

This document applies to liquid contact scale flow regulators for medical infusion and blood transfusion equipment:

2 Normative reference documents

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

GB 8368 Disposable infusion set gravity infusion type (GB 8368-2018, ISO 8536-4:2010, MOD) GB/T 16886.1 Biological evaluation of medical devices Part 1: Evaluation and testing during risk management process (GB/T 16886.1-2022, ISO 10993-1:2018, IDT)

3 Terms and definitions

The following terms and definitions apply to this document:

A component with a scale mark and in contact with the chemical liquid, used to set a specific flow rate:

flowflowrate

The volume of liquid flowing through the pipeline per unit time:

scalescale

A series of identifiers and corresponding identification numbers associated with the observed indicator position:

4 Design

Scale flow regulators should be designed for constant flow regulation: Graduated flow regulators should be designed to be used safely to avoid inadvertent flow external changes, and the "OPEN" and "OFF" positions should be clearly indicated:

A typical design of a graduated flow regulator is shown in Figure 1: