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

GB/T 43277.1-2023

**Clamps and flow regulators for medical infusion and
transfusion equipment - Part 1: Clamps and flow regulators
without fluid contact**

医用输液（输血）器具用止流夹和流量调节器 第1部分：非液体接触式止流夹和
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 1 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 8536-14:2016 "Medical infusion equipment - Part 14: Non-liquid contact medical infusion (blood transfusion) equipment" Equipped with flow stop clamp and flow regulator:

Compared with ISO 8536-14:2016, this document adds A:1:5 to the structure:

The technical differences between this document and ISO 8536-14:2016 and their reasons are as follows:

---Deleted "In addition, the materials of the stop clamp and flow regulator described in all clauses shall be in accordance with ISO 10993-1" in the "Materials" chapter "Evaluation of the requirements" (see Chapter 5 of ISO 8536-14:2016), this document relates to the non-contact of the stop clamp and the flow regulator Liquids whose materials do not require biological evaluation;

--- Added the content of test methods to prevent liquid leakage (see A:1:5), because the requirement in 6:3 "should be able to prevent the flow of liquids and gases" "Motion", while ISO 8536-14:2016 only describes the test method to prevent gas leakage;

---The test steps of the physical test have been changed and the calculation formula has been added (see A:2:4 and A:2:5) to improve the operability of the test:

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

---Added note A:2:5:

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
Regulators Part 1: Non-liquid contact stop clamps and flow regulator

1 Scope

This document specifies the design, material and physical requirements for non-liquid contact stop clamps and flow regulators used in medical infusion and blood transfusion equipment:

This document applies to the design, production and testing of non-liquid contact stop clamps and flow regulators for medical infusion and blood transfusion equipment:

2 Normative reference documents

This document has no normative references:

3 Terms and definitions

The following terms and definitions apply to this document:

Stop clamp

Parts that act on infusion/blood transfusion equipment from the outside in a non-liquid contact manner and have an "on/off" function for stopping or starting the flow of blood:

Liquid flow through the pipeline:

flowregulator Parts of infusion/blood transfusion equipment acting externally in a non-liquid contact manner, with or without graduations, used to control liquids through lines flow:

flowflowrate

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

4 Design

Non-liquid contact flow stop clamps and flow regulators should be designed to control the delivery of fluids in infusion and blood transfusion devices: non-liquid contact Stop clamps and flow regulators should be designed to be safe to use, avoid accidental operation, and should not puncture or damage the hose during operation:

Typical designs of non-liquid contact stop clamps and flow regulators are shown in Figures 1 to 3:

Figure 1 Design example of a compression flow stop clamp