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

JB/T 20206-2022

**Temperature control units for biopharmaceutical reaction
processes**

生物制药反应过程温控装置

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" drafting.

1 Scope

This document specifies the classification and model, requirements, test methods, inspection rules and instructions for the use of signs of temperature control devices for biopharmaceutical reaction processes. Instructions, packaging, transportation and storage.

This document is applicable to process temperature control devices that can realize orderly heat transfer and control through public energy in the biopharmaceutical reaction process. (hereinafter referred to as the temperature control device).

2 Normative references

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

GB/T 150 (all parts) pressure vessels

GB/T 151 heat exchanger

GB/T 191 Packaging, storage and transportation icon marks

GB/T 1226 General pressure gauge

GB/T 3768 Acoustic sound pressure method for measuring sound power level and sound energy level of noise sources adopts the simple method of enveloping the measuring surface above the reflecting surface. easy method

GB/T 4272 General Rules for Equipment and Pipeline Insulation Technology

GB 5749 Hygienic Standards for Drinking Water

GB/T 6388 Transport packaging receipt and delivery marks

GB/T 9969 General Rules for Instructions for Use of Industrial Products

GB/T 10111 Generation of Random Numbers and Its Application in Product Quality Sampling Inspection

GB/T 12241 General requirements for safety valves

GB/T 13306 Signage

GB/T 13384 General Technical Specifications for Packaging of Mechanical and Electrical Products

GB/T 36035 General Requirements for Electrical Safety of Pharmaceutical Machinery

JB/T 20188-2017 Pharmaceutical machinery product model compilation method

TSG21 Safety Technical Supervision Regulations for Stationary Pressure Vessels

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Temperature control unit

Integrated controls for precise temperature control during heat transfer.

3.2 Unit independent mode

The mode of orderly energy transfer for only one temperature control point.