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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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YY 0054-2023

Haemodialysis equipment

血液透析设备

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Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for Standardization - Part

1.Rules for the Structure and Drafting of Standardizing Documents. This Document replaced YY 0054-2010 Hemodialysis Equipment. Compared with YY 0054- 2010, this Document mad ethe major technical changes as follows besides the structural adjustments and editorial modifications.

--- Change the "Scope" (see Clause 1 of this Edition; Clause 1 of the 2010 Edition);

---Change the "Normative References" (see Clause 2 of this Edition; Clause 2 of the 2010 Edition);

--- Change the "Terms and Definitions" (see Clause 3 of this Edition; Clause 3 of the 2010 Edition);

---Change the "Classification and Basic Parameters" (see Clause 4 of this Edition; Clause 4 of the 2010 Edition);

--- Change the requirements and test methods for "blood flow error" (see

6.2.1 of this Edition;

6.2.1 of the 2010 Edition);

--- Change the requirements and test methods for "dialysate flow error" (see

6.2.2 of this Edition;

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6.2.2 of the 2010 Edition);

--- Change the requirements and test methods for "net dehydration control" (see

6.2.3 of this Edition;

1 Scope

YY 0054 is the mandatory Chinese standard for haemodialysis equipment, the machine that circulates a patient's blood through a dialyser and returns it. It sets the requirements such a machine has to meet and the test methods that verify them, covering the accuracy of the dialysate composition and temperature, the control of ultrafiltration, the blood pump and pressure monitoring, and the alarms and protective systems that detect air, leaks and disconnection. A dialysis patient is connected to the machine for hours at a time, three times a week, for years, so an error the machine does not catch has consequences no clinician can reverse. Being a YY standard without the /T suffix, compliance is compulsory in China. The 2023 edition takes effect in January 2026, which is the date manufacturers and importers have to work back from.

This Document specifies the classification and requirements of hemodialysis equipment and describes its test methods.

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2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

GB 9706.1 Medical electrical equipment - Part

3 Terms and Definitions

For the purposes of this Document, the terms and definitions given in GB 9706.216 and the following apply. The process that the equipment automatically controls the ratio of hemodialysis concentrate and dialysis water to prepare dialysate that meets clinical requirements.

4 Classification

The equipment can be divided into hemodialysis type and hemodiafiltration type.

5 Requirements

For a typical 4-hour dialysis treatment, at any time during the treatment period, the

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difference between the actual cumulative net dehydration volume and the expected cumulative net dehydration volume shall be within ±400mL. For online equipment, the equipment's replacement fluid flow control range and control error shall comply with the manufacturer's specifications.

5.7.3

c) of this Edition];

--- Change the requirements and test methods for "blood leakage protection system" (see

6.9 of this Edition;

6.9 of the 2010 Edition);

--- Change the requirements and test methods for "prevention of air ingress" (see

6.10 of this Edition;

6.10 of the 2010 Edition);

--- Change the expression of the requirements for "pH measuring device" (see

5.11 of this Edition;

5.11 of the 2010 Edition);

---Delete the requirements and test methods for "weighing scale" (see

6.12 of the 2010 Edition);

--- Change the requirements and test methods for "network power supply interruption" (see

6.12 of this Edition;

6.7.3

b) of this Edition];

--- Change the test method for "dialysate flow, temperature, conductivity stability" (see

6.8 of this Edition;

6.8 of the 2010 Edition);

--- Change the test method for "blood leakage protection system test" (see

6.9 of This Edition;

6.9 of the 2010 Edition);

---Delete "Inspection Rules" and "Marking, Instruction Manual, Packaging, Transportation and Storage" (see Clauses 7 and 8 of the 2010 Edition). Please note some contents of this

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