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

YY/T 1938-2024

Medical sodium hyaluronate dressing

医用透明质酸钠敷料

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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. Please note that some of the contents of this document may involve patents. The institution does not bear responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Medical Protective Equipment Standardization Working Group (SAC/SWG30). This document was drafted by: Bloomage Biotech Co., Ltd., Shandong Medical Device and Drug Packaging Inspection Institute, Beijing Medical Medical Device Inspection Institute (Beijing Medical Biological Protection Equipment Inspection and Research Center), Jinan Pansheng Biotechnology Co., Ltd., Shandong Sili Medical Technology Co., Ltd., Nanjing Tianzong Yikang Biotechnology Co., Ltd., and Shandong Tongqi Medical Technology Co., Ltd. The main drafters of this document are. Guo Xueping, Bo Xiaowen, Li Fan, Fu Jie, Wang Lixia, Luan Yuanyuan, Zhang Ping, Zhang Ting, Zheng Xiaofeng, Gai Xiaoxiao, Tian Xin, Xu Nianqin and Tian Xiaolei. Medical Sodium Hyaluronate Dressing

1 Scope

YY/T 1938 is the product standard for the medical sodium hyaluronate dressing, one of the highest-volume wound care products in China and a category where the line between a device and a cosmetic is commercially contested. It specifies the requirements, the marking and the packaging for these dressings and describes the corresponding test methods. Hyaluronate dressings are judged on the molecular weight and purity of the hyaluronate, the physical form of the dressing and its behaviour on the wound, and the standard is what makes those claims comparable between products. It sits alongside YY/T 1947 on recombinant collagen dressings in the group of Chinese standards covering biologically derived wound care. For a manufacturer or an importer seeking Chinese registration of a

hyaluronate dressing, this is the governing product standard.

This document specifies the requirements, labeling and packaging of medical sodium hyaluronate dressings and describes the corresponding test methods. This document applies to medical sodium hyaluronate dressings. This document does not apply to medical sodium hyaluronate dressings containing antibacterial or pharmaceutical ingredients.

Note. This document provides reference for the requirements and test methods of cross-linked sodium hyaluronate dressings for medical use.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 6682 Specifications and test methods for water used in analytical laboratories

GB/T 16886.1 Biological evaluation of medical devices Part

3 Terms and definitions

The terms and definitions defined in YY/T 1571 apply to this document.

4 Product Type

Medical sodium hyaluronate dressings are usually in the form of liquids/sprays, gels, patches, etc.

5 Requirements

5.1 Appearance There should be no visible foreign matter.

5.2 Size and loading

5.2.1 Dimensions (if applicable) Should be within the range specified by the manufacturer.

5.2.2 Filling quantity (if applicable) It should meet the requirements of Table 1.

Note. The amount of medical sodium hyaluronate dressing in the form of an application is measured by weight.