

制造商：安吉县慧峰医用敷料有限责任公司 Anji Huifeng Surgical Dressings Co.,Ltd	公司地址：浙江省安吉县晓墅工业园区 Address: Xiaoshu Industrial Zone, Anji County, Zhejiang	
文件名称：产品规格书 File Name : Product Specification	产品名称：网状绷带 Product name : Net bandage	
文件编号：HF/QR QA-15205020250613001 File No. : HF/QR QA-15205020250613001	页码：共 5 页, 第1页 Page1 of 5	

1. 适用标准 The applicable standards

No.	ISO, AAMI, ASTM Standard	Description
1	EN ISO 13485-2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
2	EN ISO 10993:2010	Biological evaluation of medical devices

2. 产品列表 The product list

No	REF CODE	UDI-D-CODE	Product	Specification	Clip
1#	HFYS012	06972915823064	Net bandage Latex free	1.7cm x25 m (stretched)	N/A
2#	HFYS020	06972915823149	Net bandage Latex free	7.2cmx25 m (stretched)	N/A

备注：以上尺寸可以按照客户要求增加 The above dimensions can be increased according to customer requirements

3. 产品规格 Product specification

3.1 产品图 Product Drawing



3.2 产品及包装材料组成 Products and Packing Materials

3.2.1 产品材料组成 Products Materials

Product	Material
Net bandage Latex free	Spandex 65% and polyester 35%
备注 note: White	

4. 检验要求 Inspection requirements

- 4.1 目视检查（检查水平可根据质量指标进行修改） Visual Inspection(Inspection levels may be modified based on quality metrics)

Attribute	Acceptance Criteria	Test Method	Defect Type Mi = Minor MA= Major C = critical	Inspection Level (A.Q.L)
Bandage appearance	No obvious hole, broken edge, and loose thread should be <1". Hair or blood is not allowed. No other obvious foreign substances on products (except cotton seed).	By visual	MA	S-3, AQL=4.0
Printing	Print is right and clear, the bar code could be easy to scan	By visual & scanning	MA	S-3, AQL=1.5
Package method	According to specification requirement	By visual	MA	S-3, AQL=1.5

4.2 尺寸检验(检验水平可根据质量指标修改) Dimensional Inspection (Inspection levels may be modified based on quality metrics)

Inspection item	Tolerance	Acceptance dimension	Test Method	Defect Type Mi = Minor MA= Major C = critical	Inspection Level (A.Q.L)
#1: Width size	Average up to standard specification	1.7cm $\pm$ 0.4cm 7.2cm $\pm$ 1.0cm	Ruler / caliper	MA	S-1 AQL=6.5
#2: Stretched Length	$\pm 8\%$	25m $\pm 8\%$		MA	

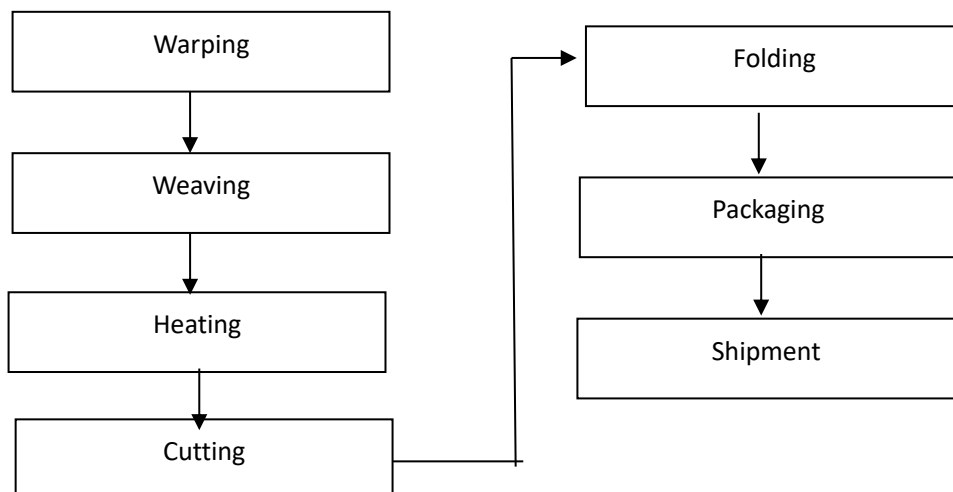
4.3 性能检测 Functional Inspection (Inspection levels may be modified based on quality metrics)

Attribute	Test Method / Acceptance Criteria	Standards (if any)	Test Equipment	Defect Type Mi = Minor MA= Major C = critical	Inspection Level (A.Q.L)
Stretched rate (length) Latex	Cal. (Stretched length/natural length $\times 100\%$)	$\geq 300\%$	By ruler	MA	S-1, AQL=6.5
Stretched rate (length) Latex free	Cal. (Stretched length/natural length $\times 100\%$)	$\geq 250\%$	By ruler	MA	S-1, AQL=6.5

5.保质期 Sterilization/ shelf life

Inspection item	Requirement
Shelf life	3 years

6.生产流程 Process flow



7.包装 Packaging

7.1 包装方式 packing way

Item No	size	Packing way
HFYS012	Net bandage Latex free	1pc/box, Several boxes/carton
HFYS020	Net bandage Latex free	1pc/box, Several boxes/carton

Note: 1、packaging can be carried out according to customer requirements, or our company designs packaging

2、A twin - watt carton is recommended for each carton over 10kg

3、Special specifications are subject to customer's request

9.修改历史 Modify history

版本 version	修改状态 Modify the state of	修改内容 Modify the content	修改人员 Modify staff	修改日期 Modification date
A	0	新建 New files	邹庆颀 Zhou Qinjie	2025.06.13