



HEFEI MLUSH SANITARY PRODUCTS CO.,LTD

Add:West Wei A Road,Yaohai Industrial Park,Xinzhan District,Hefei City,Anhui Province,China.

Technical documentation

Dental bibs

1. Introduction of Manufacturer

1.1 Introduction of the Manufacturer

HEFEI MLUSH SANITARY PRODUCTS CO.,LTD which is a professional manufacturer specialized in ,Dental Bib

Our company has obtained ISO13485 certification, Own CE certification

1.2 Basic information of the Manufacturer

Applicant: HEFEI MLUSH SANITARY PRODUCTS CO.,LTD

WestWei A Road, Yaohai Industrial Park, Xinzhan District, Hefei City, Anhui Province, China

Building 2 Industrialization Plant.Wei 4 Road, XintanQ Town, ChanRieng County. Hefei City,

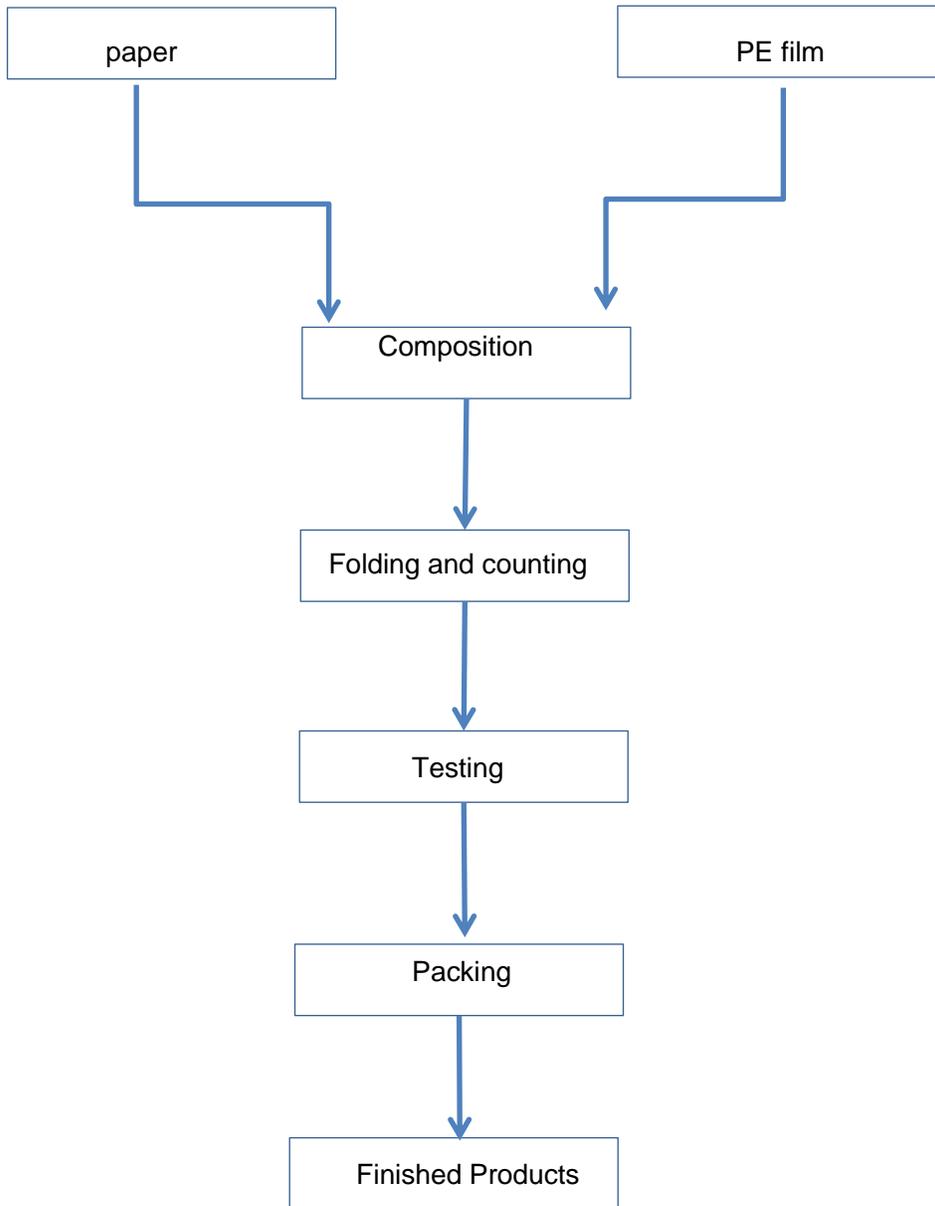
2.2 Product Information

Name	Description	Material	Picture

Dental bibs	Used as a protection against infection or water resistance in dental use. Non-sterile, single use.	Paper and PE	
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3. Process chart

3.1 Dental Bib Process chart



4. Instruction for User

4.1 Dental Bib instructions

[Product name] Dental Bib

Classification: **Restricted**

[Application] Used as a protection against infection or water resistance in dental use.

[Methods] 1. make one picec unfolded and paper frontside and PE backside

2. put bib on the chest of patient and meke it fixed.

[Duration] Three years

[Storage] Cool and dry



[Note] Single use



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5. Label and Language

5.1 General

This Clause contains symbols that are already in use, and are deemed to be suitable without need for further explanation.

NOTE Symbols used with medical devices for use by other than healthcare professionals can require additional explanations.

5.2 Symbol for "DO NOT REUSE"



NOTE 1 Synonyms for "Do not reuse" are "single use", "Use only once"

5.3 Symbol for "BATCH CODE"



This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol

NOTE 1 The relative size of the symbol and the size of the batch code are not specified.

NOTE 2 Synonyms for "batch code" are "lot number", "batch number".

5.4 Symbol for "DATE OF MANUFACTURE"



This symbol shall be accompanied by a date to indicate the date of manufacture, expressed as given in ISO 8601, as four digits for the year, and where appropriate, two digits for the month and

two digits for the day. The date could be a year, year and month, or year, month, and day, as required by the relevant Directive. The date shall be located adjacent to the symbol

NOTE 1 The relative sizes of the symbol and the date are not specified.

5.5 Symbol for "CAUTION"



NOTE 1 This symbol is essentially a safety symbol and should be used to highlight the

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fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the label. The symbol “Caution” is still sometimes used to have the meaning of “Attention, see instructions for use”

5.6 Symbol for "MANUFACTURER"



This symbol shall be accompanied by the name and the address of the manufacturer (the person placing the device on the market), adjacent to the symbol

5.7 After passing CE certification, mark of CE needs to be printed on labels;



- a) Pattern
- b) Diameter of the pattern shall not be less than 5mm.
- c) CE marking shall be distinct, visible durable and in clear writing.

6. EC Declaration of Conformity

See Declaration of Conformity