



TECHNICAL DATA SHEET

Absorbent Cotton Roll

1. General Information

1.1 General

Since 1990 our company was established and put into production. We have produced absorbent cotton (including cotton roll ,cotton balls ,cotton pad) and the device is distributed in Europe Union market, North America market and Southeast Asia market . We can do product testing independently according to BP, EP, USP standard or other international standards.

In 2005, we got the certificate of ISO13485 form TUV Products Service GmBH, Germany. The device has been registered in FDA and got the CE certificated.

We can assure you the higher and more stable quality by our strict QA/QC systems.

1.2 Product characteristics

S/N	Item		Content
1	Description		It is made of bleached absorbent cotton
2	Composition		100% cotton
3	Specification /size		100g
4	Performance	Foreign fibers	All is cotton fibers, little fibers is acceptable
5		Water absorbability	Sinking time ≤10 seconds
6		Fluorescence	No intense blue fluorescence
7		Acidity and alkalinity	Neutral
8		Surface-active substances	Can not cover the whole surface of liquid
9		Water-soluble substances	≤0.5%
10		Ether-soluble substances	≤0.5%
11		Loss on drying	≤8%
12		Sulphate ash	≤0.40%
13		Absorption capacity	≥23g/g
14	Quality requirement standard		EN14079:2003
15	Shelf life &Storage condition		Shelf life 3 years. storage at temperature 0~45°C and RH 10%~70%, Store in dry and ventilated place and not exposed to strong light.
16	Transport information		This product is not classified as " dangerous" for transport purposes.



1.3 Biocompatibility

Kingphar medical products comply with the requirements of the standard for biocompatibility of medical devices,

ISO10993-1 Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing.

EN ISO10993-5 Biological evaluation of medical devices. Part Five Tests for in vitro cytotoxicity,

EN ISO10993-10 Biological evaluation of medical devices. Part Ten Tests for irritation and delayed-type hypersensitivity

1.4 Classification

Refer to Classification rule 4 of Medical Device regulation (MDR 2017/745), non-sterile absorbent cotton for single use is classified as Class I medical device.

1.5 Intended use

Absorbent cotton is mainly used for cleaning of the skin and makeup.

2. Contraindication and attention

1. Use prohibited in case of damaged packaging or expiry.
2. This product is sterilized and can be for directly use. The sterilization can be considered depending usage purpose for the other products.
3. Disposable products and for single use only.
4. Check the package is not opened ,sealing integrity before use.
5. To be disposed according to hospital or healthy administration's requirement.

3. Special storage and operating conditions

The product shall be protected from moisture during transportation, It should be sealed and packed, and stored in a ventilated, dry and non-corrosive gas environment. Keep away from ignition sources and inflammable materials.