

Instruction for use

1. Product name: Alcohol Pads

2. Model specifications: D-020

3. Contact information

[Manufacturer]:

Company name: Wuxi Medical Instrument Factory Co.,Ltd

Address: No.43 Xixin Road ,Zhangjing , Xibei Town,Wuxi City,Jiangsu 214194 China

Tel: +86-510-83791818

Email: wxmedical@vip.126.com

[European union authorization representative]:

Company name: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e Verd,2595AA,The Hague, Netherlands.

Tel: +31644168999

Email: peter@lotusnl.com

4. Storage requirements

The packaged products shall be stored in clean, dark, non corrosive and well ventilated rooms with relative humidity no more than 80%. The transportation conditions shall be in accordance with the order contract, and shall be handled with care to prevent heavy pressure, direct sunlight and rain and snow.

5.Warning

5.1 Check whether the package is in good condition before use, confirm the package identification, production date and validity period and use them within the validity period.

5.2 This product is disposable and non-sterile, should be disposed as medical waste after use.

5.3 Alcohol is flammable. Do not contact fire or high temperature, and pay attention to electrostatic protection.

5.4 Wear protective gloves when using this product for cleaning.

5.5 The product must be used in according to the cleaning time specified in the instructions to achieve the disinfection effect.

5.6 When the product is used, there should be no liquid on the surface to avoid dilution of the product disinfection ingredients, resulting in the inability to achieve the disinfection effect.

5.7 Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

5.8.Reuse may result in inadequate disinfection or cross-infection

6.Intend purpose

6.1 Intended purpose including any clinical claims

Disinfection For solid surface of non-invasive medical devices Only.

6.2 Expected operating environment:

It can be used in Professional medical institutions or at home.

6.3 Intended user:

Natural person or medical personnel.

7. Use method

Before using this product for disinfection, clean the surface of the device to ensure that the surface to be disinfected is free of stains. The area for disinfection should not be more than 19.5cm² (area of non-woven). Tear open the package of small pieces, take out the non-woven pieces containing disinfectant with index finger and thumb, wipe and disinfect the solid surface of non-invasive medical devices that need to be cleaned 2-3 times, and make sure that the disinfectant solution on the product has completely covered the surface to be disinfected, and act for 5 minutes to achieve the disinfectant effect. After use, put the used alcohol disinfectant tablets into the appropriate trash.

8.Shelf life: 5 years

9.Main performance indicators of the product:

Relevant standards:

bactericidal (EN 13727:2012+A2:2015)

fungicidal (EN 13624:2013)

bactericidal and/or fungicidal (EN 13697:2015+A1:2019)

bactericidal and yeasticidal (EN 16615:2015)

Products show the required microbial reduction of $\geq 5.0 \log_{10}$ against test strains

Enterococcus hirae ATCC 10541

Escherichia coli K12 NCTC 10538

Pseudomonas aeruginosa ATCC 15442

















Staphylococcus aureus ATCC 6538

products show the required microbial reduction of $\geq 4.0 \log_{10}$ against test strains

Candida albicans ATCC 10231

Aspergillus brasiliensis ATCC 16404

10.Symbol

	Batch code		Please don't reuse it.
	Please read the instructions for use carefully before using.		Medical Device
	Warning and attention , please refer to the instructions for use.		Manufacturer
	Authorized representative in the European Community		Keep dry.
	Non-sterile		Do not use if package is damaged.
	Date of manufacture		Use-by date
	CE marking		Keep away from sunlight
	Importer		Distributor

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