Wuxi Kangyou Medical Products Co., Ltd

CE Technical File

of

Alcohol Swabs/Pads

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Device description

5.1 Product Name and Models

Device name:

Alcohol Swabs/Pads

Model & Specifications

6*3cm, 6.5*3 cm, 8*4 cm, 5.6*2.8 cm

5.2 Intended use

Intended use:

This product is intended to be used for disinfecting non-invasive medical devices in hospital.

Intended User:

Medical personnel

5.3 Precautions, Warnings, Contraindications, Side-effects

Contraindications:

- Disinfection of skin
- Open wound
- Skin infection or malignancy

Precautions:

1. Flammable, keep away from fire and flame.
2. Keep out of reach of children.
3. If swallowed, get medical help or contact a poison control center immediately.
4. Ethanol alcohol may cause burning, stinging, or a cold feeling.
5. This is single-use device. A reprocessing and re-use of the device is not allowed. An infection or transmission of diseases could occur, if the device were to be re-used.

5.4 Product Description

The Alcohol Swabs/Pads is intended to be used for disinfecting non-invasive medical devices in hospital. The product contains 70% isopropyl alcohol.The products at least a 5 Log reduction on 5 min on Staphylococus aureus, Escherichia coli, Pseudomonas aeruginosa, at least a 4 Log reduction on 5 min Candida albicans.It is a single use and non-sterile device.

5.5 Functional Description

The alcohol pad contains 70% isopropyl alcohol. Isopropyl alcohol is considered a universal solvent, as its molecular structure allows for the dissolving of both polar, hydrophilic and nonpolar, hydrophobic compounds. It is used widely and safely in medicine for long history. Therefore, the alcohol pad can easily remove soils on the non-invasive medical devices which is to be treated.

5.6 Product component

The product consists of spunlace non-woven fabrics, medical alcohol (70% isopropyl alcohol), aluminum foil paper and other components.

The Alcohol Pads has the following characteristics/features:

- Ready for use.
- Small pack, available quickly.
- No residue after use.

Picture:

5.7 Main Raw materials and Contact

No.	Applied Part Name	Material Designation	Contact Patient's Body	Contact Time
1	70% Isopropyl Alcohol	Isopropanol solution	Surface medical device: Intact skin	Limited: ≤24h
		Purified water	Surface medical device: Intact skin	Limited: ≤24h
2	Aluminum foil paper	Alumium	/	/
		Paper	/	/
		Nucrel	/	/
		Plastic Particles	/	/
3	Non-woven	Non-woven	Surface medical device: Intact skin	Limited: ≤24h

5.8 Use in conjunction with other medical devices

N/A

5.9 Storage

Product should be stored in the relative humidity is not more than 80%, no corrosive gas, a cool, dry, well ventilated and clean environment.

5.10 Shelf-life

5 years

5.11 Product Specifications

Table 1 Dimension of Alcohol Swabs/Pads

Specification size (cm)	Tolerance	Weight (g/Piece)	Tolerance
6*3	±0.2	0.85	±0.05
6.5*3	±0.2	0.85	±0.05
8*4	±0.2	1.4	±0.1
5.6*2.8	±0.2	0.7	±0.05

Table 2 Performance requirements

No.	**Property**	**Requirement**
1.	Dimension	Comply with Table 1.
2.	Appearance	The appearance should have no printing residue, no pollution, no damage.
3.	Laboratory test of 70% Isopropyl alcohol.	Colourless transparent liquid, Typical odor of isopropyl alcohol Isopropyl alcohol content ranges from 68.0%~72.0%
4.	Sealing	The product shall be under 5N pressure without leakage.
5.	Weight	Comply with Table 1.
6.	Bioburden	The bioburden should ⩽ 100cfu/ piece
7.	Bactericidal activity	The products at least a 5 Log reduction on 5 min on Staphylococus aureus, Escherichia coli, Pseudomonas aeruginosa,
8.	Fungicidal activity	The products at least a 4 Log reduction on 5 min Candida albicans.

5.12 Product Historical Briefing

We started to develop Alochol Pad in 2004, and improved all technology during our manufactures, such as increase every piece of liquid content, and improve the machine production speed.

Product verification and validation

The performances and characteristics of the device have been determined based on the intended purposes of the device, essential safety and performance requirements and the identified risks that might happen during the transport, storage and usage. Those factors and the verification result thereof are summarized in the following sections to provide evidence of conformity with the essential safety and performance requirements.

10.1 Biocompatibility evaluation

Product biocompatibility was evaluated according to EN ISO 10993-1. Based on the test results of type examination report for Alcohol Swabs/Pads issued by competent authority, concerning cytotoxicity, irritation, sensitization. it is concluded that the biocompatibility of the product is in line with essential safety and performance requirements from MDR.

- File # KY/CE-01-0601 Product biocompatibility evaluation report.
- Folder # Biocompatibility Test Report

Report Name	Test Method	Test requirements	Report No.	Issued date	Conclusion
In Vitro Cyotoxicity test report	EN ISO 10993-5:2009	The cytotoxicity of the device shall be no more than Grade 1.	SDKW-M201403268	2014-10-27	Accord
Skin Irritation test report	EN ISO 10993-10:2010	The intradermal reaction of score of the device shall be no more than 1.0.	SDKW-M201403270 SDKW-M201403271	2014-10-27	Accord
Skin Senitization test report	EN ISO 10993-10:2010	The device shall have no delayed type hypersensitivity (Sensitization).	SDKW-M201403269	2014-10-27	Accord

The test results meet the requirements of EN ISO 10993-1 and have good biocompatibility.

10.2 Product performance test

The test of finished products concerning physical and chemical properties related to clinical application have been performed. All test results were up to Standards for medical device registration, Test Conclusion is Qualified.

The self-test or Bench test reports of finished products are provided in Folder.

- Folder # Product Performance Test Report

Report Name	Report No.	Issued date	Conclusion
Bactericidal activity test report(Before aging)	721662872-1.1	2021-04-29	Accord
Fungicidal activity test report(Before aging)	721662872-1.2	2021-04-29	Accord
Bactericidal activity test report(Before aging)	721662872-1.1	2021-04-29	Accord
Fungicidal activity test report(After aging)	721662872-1.2	2021-04-29	Accord
Isopropyl alcohol content test report(After aging)	721662872-2.1	2021-04-09	Accord
Isopropyl alcohol content test report(After aging)	721662872-2.2	2021-04-09	Accord
Bioburden Test report	CSTBB21040807R1	2021-05-31	Accord
Product self-test report	QP-11-F03(C/0)	2020-12-15	Accord

10.3 Usability evaluation report

The hazards and hazardous situation related to the usability have been taken into consideration during risk management process, and the mitigation measures are documented in risk management file.

Usability engineering of the device is conducted according to EN 62366-1 and the result is documented in Usability Evaluation Report.

Refer to the following reports for the scenarios tested.

- File #CE-01-0602 Usability check list
- File#CE-01-0603 Usability evaluation report.

10.4 Packaging aging and Transportation evaluation reports

10.4.1 Package description

Alcohol Pad:

Component:1pc/ aluminium foil bag

Aluminium foil bag: paper+PE +AL +Surlyn

100pcs/box, box: coated paper, 350g/M2

10000pcs/ctn

10.4.2 Product stability

The product was placed in normal temperature, natural aging, and the performance of the product and packaging was tested at 0 point and the last time point of the aging test, and all met the requirements.

Conclusion: The product meets the requirements after stability test. In order to ensure the safety and effectiveness of the product, the shelf life of the product is set to 5 years.

- Folder #CHF/TC-PH-18-03-02 Packaging aging test packaging

- Product performance after aging See 6.2 Product performance test report

10.4.3 Packaging Transportation evaluation

The transport package for Alcohol Swabs/Pads is Corrugated carton 5plys. Stimulation tests are conducted based on evaluation of the factors impact on the packaging system.

The test results showed that the Package transportation performance of the product is in line with essential requirement from MDR and safe for the intended use. If the Alcohol Swabs/Pads use the different packaging material/process/equipment, it should be revalidated of the transportation evaluation.

The Packaging Transportation evaluation reports are given in Folder:

- Folder # CN21A7C6 001_Transportation Test Report