



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO14971:2019
EN ISO15223-1:2016
ISO10993-1:2018
EN ISO10993-5:2009
EN ISO10993-10:2013
EN 1041:2008+A1:2013
EN 62366-1:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-J SUN08.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: NANJING J SUN TRADING CO.,LTD.
Address:
Rm 504, NO.66 Building, Nanjing University Science Park,
Nanjing City, Jiangsu Province, China

Product Information

Name: Medical Elastic Adhesive Bandage (Tape)
Model: LE01
GMDN: 34864
Basic UDI-DI: -
Classification: Class I, According to Rule 1, Annex VIII,
Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Leon Li

Position: GM

Date:

30.05.2021

Place: Jiangsu, China



POSI

CERTIFICATE

This is to certify that the Quality Management System of

Nanjing J SUN Trading Co.,Ltd

Business License Number: 91320106302557226G

Registered Address: 504, NO.66 Building, Nanjing University Science Park,
Nanjing City, Jiangsu Province, China

Audit Address: 504, NO.66 Building, Nanjing University Science Park,
Nanjing City, Jiangsu Province, China

applicable to

Distribution of Medical Adhesive Tape, Medical Bandage, Medical Gauze, Medical Wound Dressing, Medical Scissors, Medical Absorbent Cotton, CPR Face Mask, Cooling Gel Patch, Ice Pack, Medical Tweezers, Surgical Knife, First Aid Kit, Emergency Blanket, Triangular Bandage, Medical Gloves (PVC, nitrile, latex, PE), Medical Face Masks (Oxygen Masks, Nebulizer Masks), Disposable Medical Non-Woven Products (Face Masks, Isolation Gowns, Caps, Sleeves, Shoe Covers); Disposable Paper And Plastic Products (aprons, masks, pillowcase), Medical Emergency Splint, Alcohol Swab, CAT Tourniquet, Plastic Dental Box, Tongue Depressor, Blood Collection Tube, operating instrument set, Hemostatic forceps; Distribution of Syringes, Blood Collection Tubes, infusion apparatus (for export only) has been assessed and registered by POSI against the provisions of

ISO13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



He Shan

General Manager

Certificate Registration No: POSIMD00001

Initial issue date: 2018.05.03

Issue date: 2021.04.23

Valid until: 2024.05.02



Shanghai POSI Certification Co., Ltd.

Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai, China. Email: info@posicert.com



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Nanjing J SUN Trading Co., Ltd.
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www.jsunmedical.com



FIRST
AID

PRODUCTS CONTENT

2020



First aid

Product



JSUNFA-01
Black non-Stick fluoride coated
trauma bandage scissor

Packing Way



Size: 14.5/16/18.5 cm
Material: Carbon steel
Finish: Nickel Coated
Shape: bend shape
Packing: PP bag, insert card,
blister card, inner carton,
outer carton
Qty/CTN: 200PCS/CTN
Meas.: 25*23.5*14.5cm
G.W.: 10kg
N.W.: 9.5kg



JSUNFA-02
Stainless steel
trauma bandage scissor

Details:



Size: 14.5/16/18.5 cm
Material: Stainless steel
Shape: bend shape
Packing: PP bag, insert card,
blister card, inner carton,
outer carton
Qty/CTN: 200PCS/CTN
Meas.: 25*23.5*14.5cm
G.W.: 10kg
N.W.: 9.5kg



First aid

Product

JSUNFA-03 CPR face mask

Details:

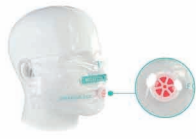


Material:clear,non-toxic PVC
Size:suitable for use of adult, child and infant
Packing way:plastic or nylon bag
Usage:it is used for patient who are in high dangerous. Easily cleaned for repeated use. pre-inflated cushion for case of application,fast and effective seal.
Features
1.CE Marked
2.With One Way Valve
3.With Plastic Case

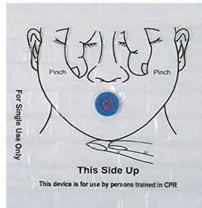


JSUNFA-04 CPR face shield

Details:



Material:clear,non-toxic PVC
Size:suitable for use of adult, child and infant
1. CPR consist of face film and one-way filter,the face shield is made of PE material.
2. The filter is made of PVC or non-woven cloth,All parts adopt high-quality eco-friendly material,free latex.
3. Each in a PP belt with key ring and color printing label on the bag or plastic box with key ring.





First aid

Product



JSUNFA-05
Malleable Aluminum
Rolled Splint

Packing Way



- 1.Material:IXPE and aluminum alloy,will not be affected by temperature and weather.
- 2.Can be well served as the fixture of broken bones.
- 3.X-ray penetration is possible for its light weight
- 4.Initial state is soft,can be changed into different shape by hand
- 5.can be penetrated by X-Ray
- 6.Size:2.5*9.5cm,45*11cm,91*100cm or customized

Roll type Plant type



JSUNFA-06
Window breaker wirh
seatbelt cutter

Details:



Lightweight Breathable Material: The arm sling is made of quality breathable mesh fiber, soft, comfortable, breathable, lightweight and durable

Easy Wearing: Suitable for most adults, professional medical treatment accessory for arm problems, can meet your different needs





First aid

Product



Tourniquet Holder



Tourniquet



Trauma Shear

JSUNFA-07 CAT Tourniquet

Packing Way



Features:

Easy application, safety set screw, dual locking

1.True, one-handed application tourniquet, used by both conventional and special operation forces

2.Proven to be 100% effective in occluding blood flow in both upper & lower extremities

3. Can be self-applied or applied by a fellow first responder

4. Quickly controls life-threatening extremity bleeding

5.Designed to perform in all weather conditions

6.Small and cost-effective

7. Tourniquet for IFAK bag



JSUNFA-08 Buckle tourniquet

Details:



Material:Buckle-Taiwan chimei

757 ABS;Belt-silk mercerized

cotton plus 32# Latex free

Features:Buckle type colorful

elastic adult tourniquet with

CE/FDA Approval;medical

product:much safer,More

Durable;buckle type tourniquet:

after disinfection,can be repeated

use;quick release tourniquet:

More convenient and comfortable



First aid

Product

JSUNFA-09 Emergency Israeli Bandages

Details:



1. **Composition:** High elastic bandage and non-sticky pad.
2. **Color:** Army Green
3. **Size:** 4' and 6'
4. **Length:** 4m or as your request.
5. **Width:** 10, 15, cm or can be customized
6. **MOQ:** 150rolls
7. **Packaging:** Available in multiple package, normal packing for individual is flow wrapped.
8. **Delivery time:** 1-25 days after samples confirmed
9. **Payment terms:** TT, paypal



Packing Way



JSUNFA-10 Triangular Bandage

Details:



Material: non woven or cotton

1. Made from 100% cotton gauze or non-woven
2. Different size available
3. Highly soft, absorbent, poison free

Strictly confirming to BP, EUP, and UPS

4. With CE, ISO certificate
5. Expiry time: 5 years
6. Packing: individually packing with 2 safety pins





First aid

Product



Material:Aluminum and foam
Color:black,white,beige,blue
Size:S 5.5cm/M 8cm/L 9cm
Feature:Helps stabilize the joints of phalange in position. stabilizes fractures of the distal phalanx;Malleable aluminum splint can be reshaped to hold fingers at an exact degree of flexion or extension;provides firm support while injuire heals; No tap required.

JSUNFA-11 Finger Splint

Details:



HOW TO USE



1: Tear off the blue film. 2: Open the Velcro bandage 3: Put your injured finger in



4: Adjust the fixed 5: Complete



JSUNFA-12 Medical Nasal Splint

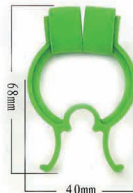
Details:



Material:PVC and foam
Packaging:1pc/poly bag,
1000pcs/carton
Certification:ISO/CE/FDA
Function:Fixation in orthopetic
surgery

Features

- 1.The product is comfortable for patient with Foam Pads.
- 2.Dual-function, nose clip for use with nebulizers or for nose bleed stoppage
- 3.Great packing with these Medical Disposable Nose Clip
- 4.Disposable, Single use





First aid

Product



JSUNFA-13
Hot Cold Pack



Details:

Material: PVC, PE+PA or Nylon+PVC
Size:

23*13cm/250g, 18.5*9.5cm/160g,
20*15cm/200g, 28*13cm/280g
or customized

Gel Color: Pantan color as per
clients'request

Packaging: poly bag or
customized(PVC bag,paper box,
PVC box,clamshell or other packaging)

Use for: Reducing swelling,toothache,
temperary relief of headache,reducing fevers



Material:
PVC, carbamide+water bag
Size:customized
Package:customized

This product can refrigerate
instantly without cold source,
convenient and portable.
Get cold within 3 seconds.

Use for: Reducing swelling,
toothache, temporary relief
of headache, reducing fevers

JSUNFA-14
Instant Ice pack

Details:



Squeeze pack to break
inner pouch,it will be
froze within 3 seconds.

1

Shake pack to mix contents
completely after activation.

2



Insert pack into soft
cover/towel.

3

Apply to affected area for
up to 20 minutes. Discard
pack after treatment.

4





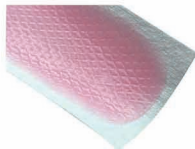
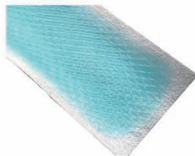
First aid

Product



JSUNFA-17 Cooling Gel Sheet

Details:



Material:

It is composed of three layers, fabric layer, gel layer, non-stick layer.

Size: 12*5cm

Feature:

As for the gel layer, it contains hydrophilic micromolecule, can reduce the heat very quickly by absorbing heat through evaporation.



JSUNFA-18 TPE disposable tourniquet

Details:



Material: TPE

Color: Blue

1 Roll include 25 pcs.

Size: 1"W x18"

1. Latex free, safer and healthier
Designed for those with Latex allergies

2. Easy use, good stretch and great quality

3. Good elasticity makes the patient feel more comfortable

How to use?





First aid

Product



JSUNFA-19 Alcohol patch

Details:



Cloth material:

non woven fabrics

Wipe size: 3x6cm or 6x6cm

Package size: 5x5cm

Warrenty: 2 years

Certification:

MSDS, ROHS, SGS, CE, ISO, FDA

Package material:

aluminum foil sachet

OEM services: welcome

Lead time:

1-3 days if in stock,

OEM order 15-20 days



Non-sterile

Material:Cotton

Mesh:40S, 19X15/24*20mesh

Size:5*5/7.6*7.6/10*10cm

Sterile:with X-Ray thread or not

Number of layers:

4ply or 8ply or 16ply

Packing way:

100pcs/box(non sterile)

10pcs/bag(sterile)

Leading time:

15-25days

Applicaiton:

Hospital,examination room,
first aid kit/box

JSUNFA-20 Gauze swabs

Details:



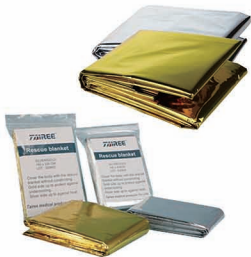
Sterile





First aid

Product



JSUNFA-15 Emergency Rescue Thermal Mylar Blanket

Details:



Gold/Silver



Silver/Silver

Material:
PET material polyester-foil(PET)
Color:Gold/silver;silver/silver
Size:
160*210,140*210,132*213cm
Thickness:
12micron
Features
1)Survival Thermal Wrap
2)Helps prevent heat loss/limits
solar exposure when used
3)Up to 90% effective reflection
of radiant energy including body heat



JSUNFA-16 Burn blanket

Details:



Material:SMS Fabric

Color:Blue

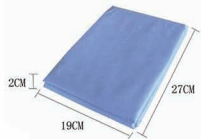
Size:60"*90"

Features

Sterile burn sheets protect
a patient from infection.
Hypoallergenic and do not
cause skin irritation.

Application:

physician offices, hospitals,
ambulance services, clinic settings,
emergency rooms





First aid

Product



Material:PE

Color:Printed Pattern

Product size:72*19MM

Certification:

CE, ISO13485,FDA

MOQ:

1. sample order 1 unit

2. formal order 10000box

Warranty:12months

Packing:

100pcs/box,100boxes/ctn

or packing according to

customers' requirement

Delivery: About 15-20 days

after deposit got and all

designs confirmed

JSUNFA-21 Wound bandage

Details:



72mm x 19mm



72mm x 25mm



76mm x 19mm



76mm x 25mm



Material:Plastic

Color:Blue,green,pink,yellow
white,

Product size:11cm/12.8cm/

Certification: ISO13485

MOQ:formal order 100000pcs

Warranty:3years

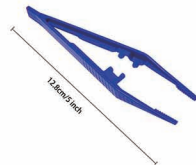
Packing:

1pc/opp bag 100pcs/bag

10000pcs/carton

JSUNFA-22 Plastic tweezers

Details:





First aid

Product

JSUNFA-23 Window breaker with seatbelt cutter

Details:



Size: 7/8.5cm

Material: Carbon steel, ABS

Shape: three types

Packing: PP bag, insert card,
inner box, outer carton

Qty/CTN: 2000PCS/CTN

Meas.: 30*30*40cm

G.W.: 15kg

N.W.: 14kg



Product regular size:
11*36cm(can be customized)

Material :

Cover non-woven fabrics
Middle High quality fluff pulp
and absorbent polymer beads;
Instant cold pack 200g
(can be customized)
Bottom Water-proof
PE cast film

Package: customized box or
customized half plastic
and half paper bag

JSUNFA-24 Perineal Cold Pack

Details:





First aid

Product



JSUNFA-25
Neck brace

Details:



Size: 16*19*16cm/17.5*21*17cm

Material: Plastic and foam

Shape: two types

Packing: PP bag, inner box,
outer carton

Qty/CTN: 30PCS/CTN

Meas.: 45*52*46cm

G.W.:10kg

N.W.:9kg

MOQ:100PCS

Application:First aid bag,
hospital, personal care.



JSUNFA-26
Head restraint
for stretcher

Details:



The patient's neck can be
immobilized in the position found.

Re-usable Length 15"
Width 10" Height 7"
Includes Straps.

Unit comes complete with base.
Two support pads and head
and chin straps.
Our Head Immobilizer conforms
to any type of backboard as well as a scoop stretcher.

