

VERIFICATION OF MDD COMPLIANCE



Applicant : SHANGHAI EMSS MED & TECH CO., LTD

Address of Applicant : ROOM 501, NO. 2, LANE 777, SOUTH ZHONGSHAN 2 ROAD, XUHUI DISTRICT, SHANGHAI, CHINA

Product Description : STRETCHER

Type and Model : EG-001 (equipped with head immobilizer & cervical collar), EG-002, EG-005, EG-006, EG-009, EDJ-002, EDJ-016A, EDJ-016B

Technical Construction File Referenced No./Rev : STT/09T1005-MDD

Codes/Standards Applied : BS EN 1865: 2000

Date Of Issuance : Jan. 5, 2009

Remarks : This Certificate Is Only Valid For The Equipment And Configuration Described, And In Conjunction With The Test Data Detailed Above.

Conclusion of Assessment :

We Hereby Confirm That The Technical Construction File And Manufacturing, Inspection And Testing Processes For Above-Mentioned Equipment Comply With The Essential Safety Requirements Of EU Medical Devices Directive 93/42/EEC Applied Codes And Standards.

Chief Assessor:

Auger Certification & Testing Service LTD.



Technical Construction File(TCF)

Document No. : STT/09T1005-MDD

According to the EC Medical Device Directive

(93/42/EEC)

Related to the

Stretcher

Date: 30- December-2008



Product discrepancy

Model	Material	Dimension	Color	--
EG-001 (two fittings)	LLDPE, PU foam fill in	184 x 45.5 x 6.5 cm	Orange	--
fitting1--Head immobilizer (EG-001-A)	foamed plastics, Polyethylene Coated	40 x 25.5 x 16.5 cm	Jacinth	--
fitting 2--Cervical collar (EG-001-B)	Special PE	57 x 17 x 2 cm	Blue&yellow&white	--
EG-002	HDPE	184 x 45 x 4.5 cm	Orange	--
EG-005	HDPE	185 x 45 x 3.5 cm	Yellow	--
EG-006	HDPE	184.5 x 45 x 5 cm	Orange	--
EG-009	HDPE	60 x 40 x 6 cm	Orange	--
EDJ-002	Special PE	162 x 44.5 x 7 cm	Yellow	--
EDJ-016A	PE	216 x 61 x 19 cm	Orange	Integrated
EDJ-016B	PE	216 x 61 x 19 cm	Orange	Detachable

Note: All the above-mentioned specification conform to actual samples. And our company will be responsible for all the consequences caused by discrepancy.

Specification of Spinal Board ' s Fittings

1) Head immobilizer (EG-001-A)

Unique head strap is designed to conform patient's forehead.

Large ear holes for monitoring the patient's bleeding

Minimal interference with X-ray, MRI, or CT procedures

Waterproof plastic coating makes it easy to prevent bacterial growth within components.

Will not absorb blood or bodily fluids

Technical parameters

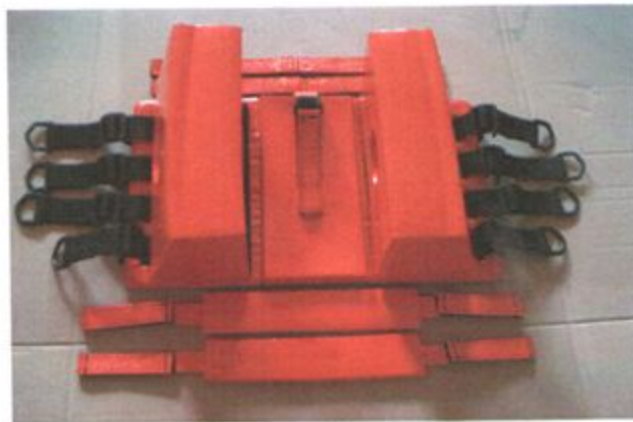
Material: foamed plastics, Polyethylene Coated

N.W: 1.7KG G.W: 2.2KG

Package size: 41 x 27 x 17cm

Standard color: Jacinth

Picture



The medical device risk management report

1 Foreword

This text is the report that carries on the risk management to the **SHANGHAI EMSS MED & TECH CO., LTD**, in the report to all of the possible harm and each reason of the harm produce on judge. and evaluate all the production of the severity and the occurrence of the harm .At the some if the risk level can't accept, adopt to lower to see of control measure, carry on an evaluation towards adopting the risk measure after of residual risk in the meantime. Last, making all levels of residual risk can accept.

2 Apply scope

This report is applicable to the **SHANGHAI EMSS MED & TECH CO., LTD** products, that product are produced in the placed of small batch a production stage.

3 Application data

3.1 related standards

- 1) Application of the ISO14971:2000--medical device-application of risk management to the medical device
- 2) The standard of product and other

3.2 The data concerning product

EMSS Spinal Board (EG-001)

Technical parameters

Material: LLDPE, PU foam fill in
through out X-ray

Product Size: 184*45.5*6.5 cm

Package: 1pc/carton

Package Size: 185*47*7.5 cm

N.W: 8. 5Kg

G.W: 10Kg

Float on water: 30kg

Load bearing: 150 kg
Color: Orange, Yellow
Without pins

Head immobilizer (EG-001-A)
Technical parameters

Material: foamed plastics, Polyethylene Coated
N.W: 1.7KG G.W: 2.2KG
Package size: 41 x 27 x 17cm
Standard color: Jacinth

Cervical collar (EG-001-B)
Technical parameters

Material: Special PE
Package: 40pcs/carton
Package size: 60*50*48cm
N.W:8kg/carton
G.W:13kg/carton

3.3 abbreviation words explain:

- 1) ALARP area: The reasonable credibility lowers area
- 2) FMEA: The expired mode and effect analysis
- 3) FMECA: The expired mode, effect and the harm degree analyze;
- 4) FTA: Top- Down the tree analysis etc.;
- 5) SEEA: software errors affect analysis

4 The product explain

4.1 General

The object of this risk management is a series of **STRETCHER**.

4.2 Use environments

This spinal board provided by our company can be used as a floatation device as well. It is completely translucent for the patient to stay in place during x-rays. It is made of one piece without seams or joins at all, so body fluids or water will never appear on the board. It is equipped with head immobilizer and cervical collar.

Unique head strap is designed to conform patient's forehead.
Large ear holes for monitoring the patient's bleeding
Minimal interference with X-ray, MRI, or CT procedures
Waterproof plastic coating makes it easy to prevent bacterial growth within components.

VERIFICATION OF MDD COMPLIANCE



**Auger
Testing
Certification**

Certificate No. AC/0481209

Applicant : SHANGHAI EMSS MED & TECH CO., LTD

Address of Applicant : ROOM 501, NO. 2, LANE 777, SOUTH ZHONGSHAN 2 ROAD, XUHUI DISTRICT, 200032, SHANGHAI, P.R.C

Manufacturer : SHANGHAI EMSS MED & TECH CO., LTD

Address of Manufacturer : ROOM 501, NO. 2, LANE 777, SOUTH ZHONGSHAN 2 ROAD, XUHUI DISTRICT, 200032, SHANGHAI, P.R.C

Product Description : First aid kits (with accessories CPR Mask, Pocket CPR Mask, Medical tourniquet, Emergency blanket and Rolled splint)

Type and Model : EX-013 (EH-001, EH-010, EF-001, EF-006, EJB-001), EX-014, EX-015

Referenced No./Rev : STT/09T1491-MDD

Directive(s) : 93/42/EEC

Date Of Issuance : Dec. 22, 2009

Remarks : This Certificate Is Only Valid For The Equipment And Configuration Described, And In Conjunction With The Test Data Detailed Above.

Conclusion of Assessment :

The CE mark as show below can be used, under the responsibility of the manufacturer or the importer, after completion of an EC Declaration of Conformity and compliance with all relevant EC Directives.

Chief Assessor:

Auger Certification & Testing Service LTD.



Technical Construction File

(TCF)

Document No. : STT/09T1491-MDD

According to the EC Medical Device Directive
(93/42/EEC)

Related to the

First aid kits (with accessories CPR Mask, Pocket CPR Mask,
Medical tourniquet, Emergency blanket and Rolled splint)

Date: 21- December-2009

With Accessories:

CPR Mask(EH-001) is made of PE+PP. It is crystal. With one-way valve to avoid any direct contact between the patient and rescuer onto mouth, nose and face. It will also help overcome fatigue to start resuscitation.

Packing: 1500 pcs/carton(individually wrapped with plastic bag)

Packing size: 61×50×35 cm

N.W: 13 kg G.W: 13.5 kg

Pocket CPR Mask(EH-010) is made of PP+PVC, including CPR Mask, Gloves and alcohol swabs each packed with plastic box. Transparent dome allows rescuer to check the color of patients' lips and vomitus visually. Inner oxygen inlet facilitates increased oxygen delivery to patient, standard connection 22 mm.

Packing: 60 pcs/carton

Packing size: 46×41×32 cm

N.W: 8.0 kg G.W: 9.5 kg

Medical tourniquet(EF-001) is made of latex thread, tight nylon & ABS buckle. With elegant appearance, more practical than the traditional rubber pipe. Enhance pressure on the arteries to stop bleeding.

Packing: 500 pcs/carton

Packing size: 34×34×29 cm

N.W: 12.5 kg G.W: 13 kg

Emergency blanket(EF-006) is made of PET. It can provide personal protection from rain, wind, heat & cold. This blanket can retain up to 90% body heat in cold weather. It even deflects heat in hot climates and can be used to offset hypothermic reactions.

Packing: 200 pcs/carton

Packing size: 37×36×27cm

N.W: 12.5 kg G.W: 13 kg

Rolled splint(EJB-001) is made from IXPE & Aluminum alloy. It is nontoxic, non-benzene and will not be affected by the temperature, climate. It can be cut at will and used repeatedly. This item of splint is applicable to army, public health service, fire controlling works, birth planning works and highly commented by customers.

Packing: 126 rolls/box

Packing size: 60 x50 x37 cm

N.W: 19 KG G.W: 21.5 KG

Note:

These products are made of environmental material.

Please do not use an improperly sized first aid product. The above mentioned contents are match the real products. We will be responsible for the difference.

Product Description:**EMSS First aid kits with accessories****1. Technical Parameters :**

1. Product size: 38.5×36×15 cm (L×W×H)

Package: 5 pcs/carton

Packing size: 80×37.5×34.5 cm

2. With accessories:

CPR Mask, Pocket CPR Mask, Medical tourniquet, Emergency blanket & Rolled splint

3. Pictures:**II. Description:****1. Features:**

This first aid kits is made of nylon which is dustproof, shockproof and easy to clean. It has accessories CPR Mask, Pocket CPR Mask, Medical tourniquet, Emergency blanket, Rolled splint and so on first aid products.

It is easy for users to get these inner accessories because of its reasonable settings .

This comprehensive using first aid kits is anti-collision, light weight and portable .It is applicable to hospital, first aid centre, rescue team of mining, defence disaster centre and so on places.

uct photos:

