

Neonatal phototherapy eye mask

CE Technical file

[File No: CE/ATL-001]

[Version: 1.0 / Date: 29th June,2011]

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Reviewed by:	Li nong	Date:29 th June,2011
Approved by:	Richard Yu	Date:29 th June,2011

Ontecklong (Nanjing) Medical Supply Corporation Limited

1. Information of Manufacturer and European authorized representative

1.1 Manufacturer

Company name: Ontecklong (Nanjing) Medical Supply Corporation Limited

Address: Bldg 10,Jinshangfang,No.288 South Xiongzhou Road, Liuhe District,Nanjing,210048
Jiangsu, P.R.China

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1.2 Quality management system

We have established and operated quality management system according to ISO13485:2003 Medical devices—Quality management systems — Requirements for regulatory purposes.(Quality manual: Q/ATL-QM-1 version A/0).All the files related to Quality system including quality manual, program, and records are stored in the relative department of our company.

1.3 European Authorized Representative

We hereby authorize M/s Empireum as our European Authorized Representative

Company: Empireum

Address: Modlinska 121, 05-110 Jablonna Poland

Contact: Piotr Dopieralski

Title: CEO

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Annex 1 European Authorized Representative agreement

2. Product description

The product covered by this CE technical file is as Chart I

Chart I Product description

Neonatal phototherapy eye protector Product model	Type I Large / Type I Medium / Type I Small / Type I Extra Small
	Type I-N Large / Type I-N Medium / Type I-N Small / Type I-N Extra Small
	Type II Large / Type II Medium / Type II Small / Type II Extra Small
	Type III Large / Type III Medium / Type III Small / Type III Extra Small
	Type IV Large / Type IV Medium / Type IV Small / Type IV Extra Small
	Type V Large / Type V Medium / Type V Small / Type V Extra Small
	Type V-N Large / Type V-N Medium / Type V-N Small / Type V-N Extra Small
	Type VI Large / Type VI Medium / Type VI Small / Type VI Extra Small
	Type VII Large / Type VII Medium / Type VII Small / Type VII Extra Small
Intended use	To protect neonatal baby's eyes by blocking the blue light during phototherapy treatment
Product description	It mainly consists of mask body, shield and adhesive tape. The main raw material is spunlaced non-woven cloth and bonding fabric. It is un-sterilized.
Product classification	The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC
Certification Approach	MDD 93/42/EEC/MDD2007/47/EEC AMEDING ANNEXVII
Standard	EN ISO 14971:2009 Medical Devices - Application of Risk Management to Medical Devices
	EN980:2008 Symbols for use in the labeling of medical devices
	EN ISO 10993-1:2009/AC2010 Biological evaluation of medical devices-Evaluation and testing
	EN ISO 10993-5:2009 Biological evaluation of medical devices-Tests for in vitro cytotoxicity
	ISO 10993-10:2002 AMD 2006 Biological evaluation of medical devices -Tests for irritation and delayed-type hypersensitivity
	EN 1041:2008 Information supplied by the manufacturer of medical devices

3.EC Declaration of Conformity

Manufacturer:

Ontecklong (Nanjing) Medical Supply Corporation Limited
Bldg 10,Jinshangfang,No.288 South Xiongzhou Road,Liuhe
District,Nanjing,210048 Jiangsu,P.R.China

whose single Authorized Representative:

Empireum, Modlinska
121, 05-110 Jablonna Poland

We, the manufacturer, herewith declare that the products

Neonatal Phototherapy Protection Mask

Model:

Type I Large / Type I Medium / Type I Small / Type I Extra Small Type I-N Large / Type I-N Medium / Type I-N Small / Type I-N Extra Small
Type II Large / Type II Medium / Type II Small / Type II Extra Small / Type III Large / Type III Medium / Type III Small / Type III Extra Small
Type IV Large / Type IV Medium / Type IV Small / Type IV Extra Small / Type V Large / Type V Medium / Type V Small / Type V Extra Small
Type V-N Large / Type V-N Medium / Type V-N Small / Type V-N Extra Small / Type VI Large / Type VI Medium / Type VI Small / Type VI
Extra Small / Type VII Large / Type VII Medium / Type VII Small / Type VII Extra Small

UMDNS-Code: 11-659

meet the provisions of Directive 93/42/EEC as amended by 2007/47/EEC which apply to them.

The medical device has been assigned to class **I** according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been **designed and** manufactured under a quality management system according to Annex **VIII** of Directive 93/42/EEC as amended by 2007/47/EEC.

Following the procedure relating to the EC Declaration of Conformity set out in **Annex VIII** of Directive 93/42/EEC.

Manufacture concerned with the conformity of the products with the metrological requirements.

The above mentioned declaration of conformity is exclusively under the responsibility of

Ontecklong (Nanjing) Medical Supply Corporation Limited.

Nanjing, 29th June, 2011

Place, date

Richard Yu

Legally binding signature, Function

4. Essential Requirements

The neonatal phototherapy eye mask is in accordance with all the essential requirements listed at Annex I, MDD93/42/EEC, MDD2007/47/EEC AMENDING

Annex II Essential requirements

5. Risk Management

We have established and operated quality management system according to EN ISO 14971:2009 Medical Devices - Application of Risk Management to Medical Devices(Risk control program file: Q/ATL-QP7.1-2, version A/0).All the risks related to this product have been reduced to be ACC.

Annex III Risk analysis report

6. Product designing description

6.1 Neonatal phototherapy eye mask

6.1.1 Intended use

Neonatal phototherapy eye mask is used to protect baby's eyes during phototherapy treatment.

6.1.2 Product description

Neonatal phototherapy eye mask can block blue light and other various strong visible light. It can protect baby's eyes well by blocking the blue light during the phototherapy treatment.

It is soft, water-absorbent, permeable, safe, without stimulation, not easy to shed-off.

It mainly consists of mask body, shield pad and adhesive tape.

The mask body is used to fix the eye mask on the head of the neonatal baby, and make sure the shield pad is placed on the eyes of the baby. It is divided as Large, medium, small and extra small according to the size.

The mask body is made by elastic bandage or elastic nonwoven cloth, which is soft, comfortable, with good permeability and elasticity.

The material can be ranked as follows:

Spunlaced nonwoven cloth, medical elastic bandage, adhesive tape, heat-sealed by ultrasonic

Elastic bonding spunlaced nonwoven cloth, adhesive tape, heat-sealed by ultrasonic.

Elastic bonding nonwoven cloth, adhesive tape, heat-sealed by ultrasonic.

Spunlaced nonwoven cloth, medical infusion stick, heat-sealed by ultrasonic.

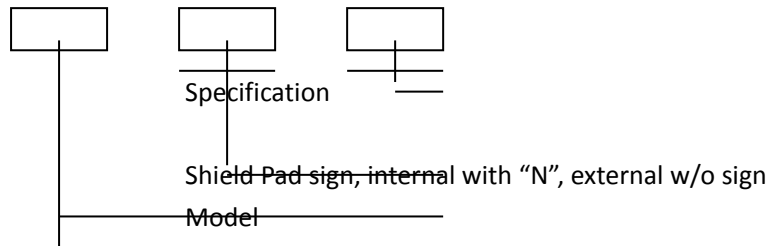
The shield pad is used to block the blue light during phototherapy treatment, which is made of blue&black physical bonding fabric. It is ranked as large, medium, small, extra small according to the size. It is pasted on the mask body or built-in fixedly.

The adhesive is on the two sides of the mask body to offer the fixing function. It is heat-sealed on the mask body by ultrasonic.

6.1.3 Model and Specification

6.1.3.1 Model and Specification definition

Model is expressed as follows:



All the models are as follows:

Type I Large / Type I Medium / Type I Small / Type I Extra Small

Type I-N Large / Type I-N Medium / Type I-N Small / Type I-N Extra Small

Type II Large / Type II Medium / Type II Small / Type II Extra Small

Type III Large / Type III Medium / Type III Small / Type III Extra Small

Type IV Large / Type IV Medium / Type IV Small / Type IV Extra Small

Type V Large / Type V Medium / Type V Small / Type V Extra Small

Type V-N Large / Type V-N Medium / Type V-N Small / Type V-N Extra Small

Type VI Large / Type VI Medium / Type VI Small / Type VI Extra Small

Type VII Large / Type VII Medium / Type VII Small / Type VII Extra Small

6.1.3.2 Model description

Chart II Model description

Content Model	Mask body				Shield pad			Characteristic
	Material	Fixing mode	Specification	Adhesive tape	Material	Position	Specification	
I	Spunlaced nonwoven cloth and medical elastic bandage	Encompassed to the head, fixed by bandage	Large, Medium, Small, Extra small	N/A	Black&blue bonding fabric	External	Large, Medium, Small, Extra small	Good permeability and fasten well
II	Elastic bonding spunlaced nonwoven cloth or elastic PP nonwoven bonding fabric	Fasten together on the cervix	Large, Medium, Small, Extra small	YES	Black&blue bonding fabric	External	Large, Medium, Small, Extra small	Good permeability and fasten well
III	Elastic bonding spunlaced nonwoven cloth or elastic PP nonwoven bonding fabric	Fasten together on the Occiput joining with forehead	Large, Medium, Small, Extra small	YES	Black&blue bonding fabric	External	Large, Medium, Small, Extra small	Good permeability and fasten well
IV	Elastic bonding spunlaced nonwoven cloth or elastic PP nonwoven bonding fabric	Back-head and cervix fasten together	Large, Medium, Small, Extra small	YES	Black&blue bonding fabric	External	Large, Medium, Small, Extra small	Good permeability and fasten well
V	Spunlaced nonwoven cloth or elastic bonding spunlaced nonwoven fabric	Fasten on the temporal	Large, Medium, Small, Extra small	N/A	Black&blue bonding fabric	External	Large, Medium, Small, Extra small	Good permeability and fasten well
VI	Elastic bonding spunlaced nonwoven cloth or elastic PP nonwoven bonding fabric	Fasten on the temporal or head	Large, Medium, Small, Extra small	YES	Black&blue bonding fabric	External	Large, Medium, Small, Extra small	Good permeability and fasten well
VII	Elastic Bonding spunlaced nonwoven cloth or elastic PP nonwoven bonding fabric	Back-head and cervix fasten together	Large, Medium, Small, Extra small	YES	Black&blue bonding fabric	External	Large, Medium, Small, Extra small	Good permeability and fasten well
I -N	Spunlaced nonwoven cloth and medical elastic bandage	Encompassedtothe head, fixed by bandage	Large, Medium, Small,	N/A	Black&blue bonding fabric	Internal	Large, Medium, Small,	Good permeability and fasten well

			Extra small				Extra small	
V-N	Spunlaced nonwoven cloth and medical elastic bandage	Fasten on the temporal	Large, Medium, Small, Extra small	N/A	Black&blue bonding fabric	Internal	Large, Medium, Small, Extra small	Good permeability and fasten well

6.1.3.3 Specification description

Model I Size

Size Specification	Mask body		Shield Pad		
	L (mm)	H (mm)	l (mm)	h (mm)	r (mm)
Large	120±15	85±15	105±10	40±10	≥0.5
Medium	105±15	75±15	95±10	35±10	≥0.5
Small	95±15	65±15	85±10	30±10	≥0.5
Extra small	85±15	55±15	75±10	25±10	≥0.5

Model I -N Size

Size Specification	Mask body		Shield Pad		
	L (mm)	H (mm)	l (mm)	h (mm)	r (mm)
Large	120±15	85±15	105±10	40±10	≥0.5
Medium	105±15	75±15	95±10	35±10	≥0.5
Small	95±15	65±15	85±10	30±10	≥0.5
Extra small	85±15	55±15	75±10	25±10	≥0.5

Model II Size

Size Specification	Mask body		Shield Pad		
	L (mm)	H (mm)	l (mm)	h (mm)	r (mm)
Large	175±15	55±15	105±10	40±10	≥0.5
Medium	160±15	50±15	95±10	35±10	≥0.5
Small	135±15	45±15	85±10	30±10	≥0.5
Extra small	115±15	40±15	75±10	25±10	≥0.5

Model III Size

Size Specification	Mask body		Shield Pad		
	L (mm)	H (mm)	l (mm)	h (mm)	r (mm)
Large	390±15	95±15	105±10	40±10	≥0.5
Medium	320±15	80±15	95±10	35±10	≥0.5
Small	270±15	65±15	85±10	30±10	≥0.5
Extra small	240±15	60±15	75±10	25±10	≥0.5

Model IV Size

Size Specification	Mask body		Shield Pad		
	L (mm)	H (mm)	l (mm)	h (mm)	r (mm)
Large	340±15	110±15	105±10	40±10	≥0.5
Medium	290±15	95±15	95±10	35±10	≥0.5
Small	230±15	85±15	85±10	30±10	≥0.5
Extra small	210±15	75±15	75±10	25±10	≥0.5

Model V Size

Size Specification	Mask body		Shield Pad		
	L (mm)	H (mm)	l (mm)	h (mm)	r (mm)
Large	155±15	45±15	105±10	40±10	≥0.5
Medium	145±15	40±15	95±10	35±10	≥0.5
Small	135±15	35±15	85±10	30±10	≥0.5
Extra small	125±15	30±15	75±10	25±10	≥0.5

Model V-N Size

Size Specification	Mask body		Shield Pad		
	L (mm)	H (mm)	l (mm)	h (mm)	r (mm)
Large	155±15	45±15	105±10	40±10	≥0.5
Medium	145±15	40±15	95±10	35±10	≥0.5
Small	135±15	35±15	85±10	30±10	≥0.5
Extra small	125±15	30±15	75±10	25±10	≥0.5

Model VI Size

Size Specification	Mask body		Shield Pad		
	L (mm)	H (mm)	l (mm)	h (mm)	r (mm)
Large	410±15	65±15	185±5	42±5	≥0.5
Medium	380±15	60±15	175±5	39±5	≥0.5
Small	355±15	55±15	165±5	36±5	≥0.5
Extra small	335±15	50±15	155±5	33±5	≥0.5

Model VII Size

Size Specification	Mask body		Shield Pad		
	L (mm)	H (mm)	l (mm)	h (mm)	r (mm)
Large	420±15	165±15	105±10	40±10	≥0.5
Medium	395±15	145±15	95±10	35±10	≥0.5
Small	365±15	135±15	85±10	30±10	≥0.5
Extra small	335±15	125±15	75±10	25±10	≥0.5

6.1.4 Product picture

Model I



Model II



Model III



Model IV



Model V



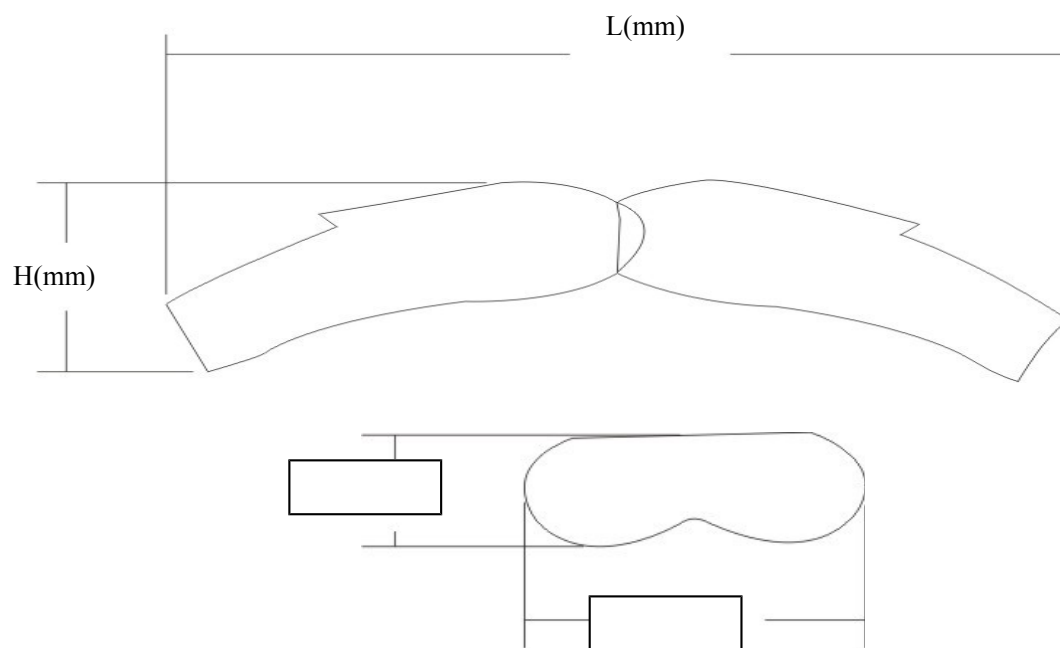
Model VI



Model VII



6.1.5 Product Design Illustration



6.1.6 Quality requirement

6.1.6.1 Physical quality

1. Appearance:
 - a) The periphery and surface of the mask body shall be without defect, dust spot. The edge of the shield pad shall be in good order, heat-sealed by ultrasonic or sewing.
 - b) The periphery and surface of the shield pad shall be without defect, dust spot. The edge of the shield pad shall be in good order.
 - c) The periphery and surface of the eye mask shall be without defect, dust spot. The edge of the shield pad shall be in good order, shield pad shall be pasted on the mask body tightly.
2. The size shall be in accordance to 6.1.3.3. Specification description
3. Fasten intensity: When fasten the mask body and shield pad by Heat-sealed by ultrasonic or sewing, It can load the vertical force from an object which weighs 0.5kg.
4. Blocking blue light: It can block the blue light and other strong visible light well.

6.1.6.2 Bio-compatibility

In consideration of the contact level(Skin contact) and contact time(Less than 24 hours),and in accordance to EN ISO10993-1:2009,the main issue related to the bio-compatibility is as follows:

- 1.Cytotoxicity shall not be more than 2.
- 2.Sensitivity response: N/A
- 3.Skin irritation: N/A

6.1.7 Raw material

Raw material and Supplier is as Chart 3

Chart 3 Raw material and Supplier

Raw material	Supplier	Key material
Elastic bonding Nonwoven cloth	Jiangyin yongshen Nonwoven Technolgy Co.,Ltd	YES
Spunlanced Nonwoven cloth	Hangzhou Nanfeng Nonven Co.,Ltd	YES
Black&blue bonding fabric	Ottobock(Germany)	YES

Chart 4 Raw material quality requirement

Rank		Nonwoven cloth	Bonding fabric
Item		quality	quality
Weight of per square meter (g)		70~305	80~500
Breaking strength	Portrait	17	100
N ≥	Landscape orientation	3.4	80
Fluorescence		N/A	

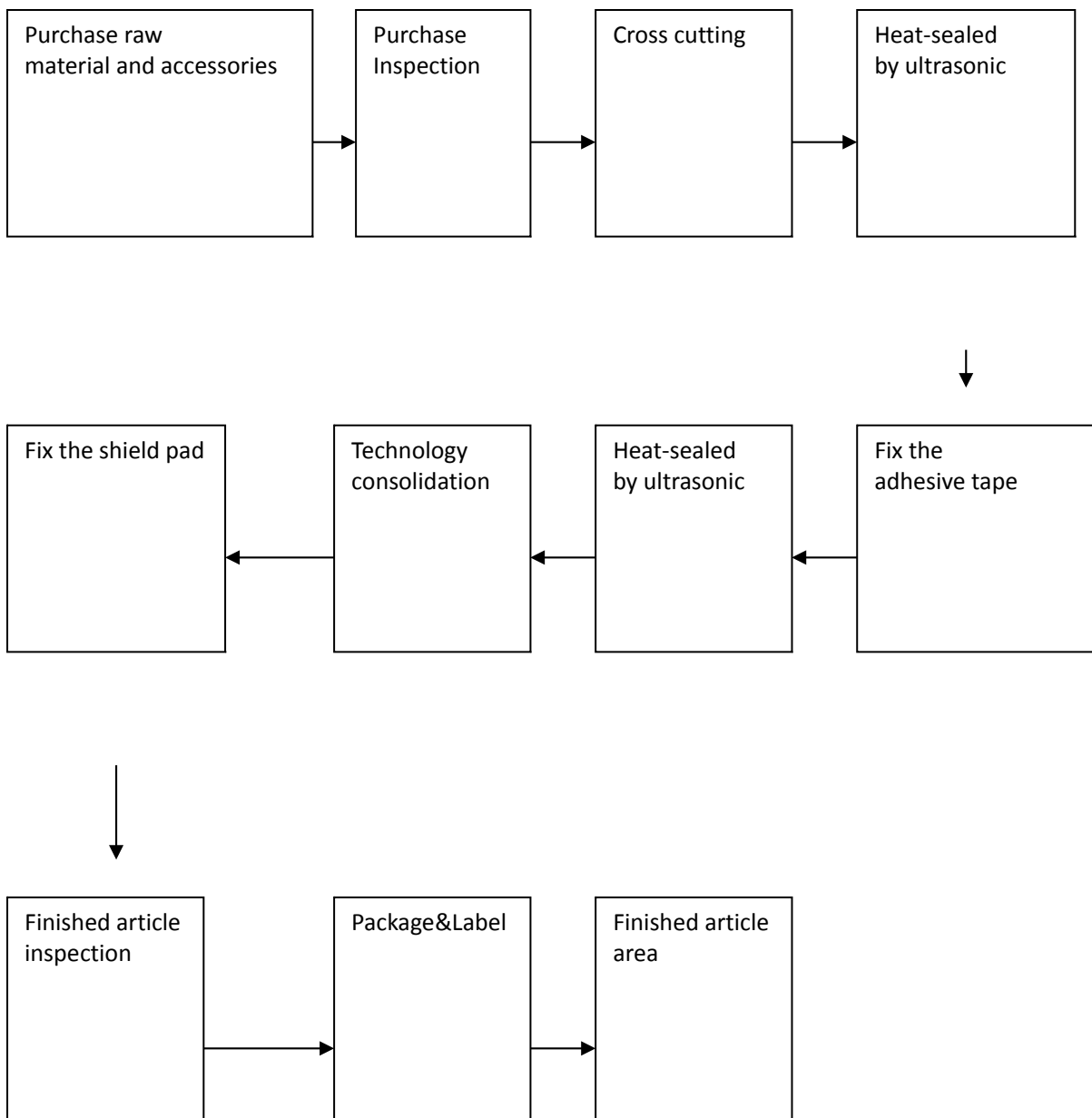
Chart 5 Accessories and supplier

Accessories	Supplier	Key raw material
Adhesive tape	Jiangmen Lujiu tape technology co.,ltd	N/A
Outer-carton	Nanjing carton co.,Ltd	N/A
Package	Anhui Anqing Baojie packing co.,ltd	N/A

7. Course of production and quality controlling

7.1 Production flow chart

Production flow chart



7.2 Quality control

Chart 6 Quality control

Inspection item	Rule	Sampling method
Stock inspection	QG-04 A/0	Random
Semi-finished article inspection	QG-04 A/0	Full
Finished article inspection	QG-04 A/0	Random

8. Quality Evaluation

The test result shows that this product is in accordance to the intended quality requirement with reference to the YZB/SU-2010 Neonatal phototherapy eye mask medical device registered product standard of Jiangsu Medical device testing center.

Chart 7 Test result

Test item	Requirement	Result	Test report no
Cytotoxicity	No more than 2	2	2010ZC966
Sensitivity response	N/A	N/A	2010ZC966
Skin irritation	N/A	N/A	2010ZC966
Appearance	The periphery and surface of the mask body shall be without defect, dust spot. The edge of the shield pad shall be in good order, heat-sealed by ultrasonic or sewing.	Qualified	2010ZC692
	The periphery and surface of the shield pad shall be without defect, dust spot. The edge of the shield pad shall be in good order.	Qualified	2010ZC692
	The periphery and surface of the eye mask shall be without defect, dust spot. The edge of the shield pad shall be in good order, shield pad shall be pasted on the mask body tightly.	Qualified	2010ZC692
Size	The size shall be in accordance to 6.1.3.3. Specification description	Qualified	2010ZC692
Fasten intensity	When fasten the mask body and shield pad by Heat-sealed by ultrasonic or sewing, It can load the vertical force from an object which weighs 0.5kg.	Qualified	2010ZC692
Blocking blue light	It can block the blue light and other strong visible light well.	Qualified	2010ZC692

9. Clinical

This product is in clinical use at department of neonatal of Jiangsu province hospital from 17 July,2008 to 11 July,2009.

The clinical evaluation is as follows:

Sunnybaby neonatal phototherapy eye mask can effective block the blue light during the phototherapy treatment and protect neonatal baby's eyes well. It offers comfortable, safe, and reliable protection solution.

This product is in clinical use at Nanjing Maternity and child health care hospital from 1 August,2007 to 30 November,2009.

The clinical evaluation is as follows:

The quality of sunnybaby phototherapy eye mask is reliable. It solves the problems of light leakage, easy shed-off, which is the best protection products for phototherapy treatment.

According to the above-mentioned clinical evaluation, this product is with reliable quality, which can protect baby's eyes by blocking the blue light effectively during phototherapy treatment. It is in accordance to the requirement of intended use.

10. Package description

Package: use medical dialysis paper or clear edible plastic bags;

Transportation: transportation can be general, but products can not be exposed to the sun, rain, harmful gases and liquids.


Storage: packaged products should be stored at a cool, dry, non-corrosive material, well-ventilated and clean environment ,with the temperature between $-10^{\circ}\text{C}\sim 45^{\circ}\text{C}$, relative humidity of not more than 80%.


11. Label/Instruction for use

11.1 Transportation label

Neonatal Phototherapy Protection Mask

CE

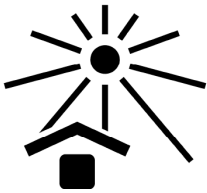
Model:	
LOT	
	
Quantity	




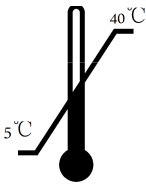
Ontecklong (Nanjing) Medical Supply Corporation Limited
Bldg 10,Jinshangfang,No.288 South Xiongzhou Road, Liuhe
District,Nanjing,210048 Jiangsu, P.R.China

EC REP

Empireum
Modlinska 121, 05-110 Jablonna Poland
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Tel: +48 22 782 44 74
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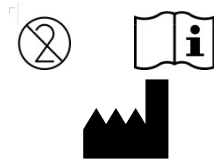


11.2 Package Label

Neonatal Phototherapy Protection Mask

LOT

Models:



Ontecklong (Nanjing) Medical Supply
Corporation Limited
Bldg 10, Jinshangfang, No.288 South
Xiongzhou Road, Liuhe District, Nanjing,
210048 Jiangsu, P.R.China



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Ver 1.0

Neonatal Phototherapy Protection Mask Instructions for Use
[CE/ATL-M-01 Ver 1.0]



Ver 1.0

Product Name

Neonatal Phototherapy Protection Mask

Cautions

1. Please read this instruction carefully prior to use.
2. Assure masks are sized correctly to prevent airway obstruction or eye damage from slippage or excessive pressure.
3. Adjust the mask body to make sure the correct position and comfortable wearing;
4. Observe the conditions during therapy; Change the masks once it has lost its stick or contaminated;
5. It is recommended to consult an eye doctor prior to use this product on patients who have eye infection;
6. This product is for single use only;
7. There might be some slight impression, local inflamed, which are normal conditions and will be disappeared once stopping using the product soon.

Models

Type I Large / Type I Medium / Type I Small / Type I Extra Small
Type I-N Large / Type I-N Medium / Type I-N Small / Type I-N Extra Small
Type II Large / Type II Medium / Type II Small / Type II Extra Small
Type III Large / Type III Medium / Type III Small / Type III Extra Small
Type IV Large / Type IV Medium / Type IV Small / Type IV Extra Small
Type V Large / Type V Medium / Type V Small / Type V Extra Small
Type V-N Large / Type V-N Medium / Type V-N Small / Type V-N Extra Small
Type VI Large / Type VI Medium / Type VI Small / Type VI Extra Small
Type VII Large / Type VII Medium / Type VII Small / Type VII Extra Small

Mask with large specification is applicable to the neonates with head circumference of 33-38 cm.

Mask with medium specification is applicable to the neonates with head circumference of 26-32 cm.

Mask with small specification is applicable to the neonates with head circumference of 20-25 cm.

Mask with extra small specification is applicable to the neonates with head circumference of 15-20 cm.

Introduction

Neonatal Phototherapy Protection Mask could effectively resist the blue light with wavelength of 425~475nm during the phototherapy in order to prevent the eye damage from the neonate patients. It is available in various materials, such as Spunlaced Nonwovens, Elastic Spunlaced Nonwovens or Elastic polypropylene non-woven fabrics; and various configurations, such as fixed or adjustable. The shield have two different kinds, external type and internal type.

The masks have the following features: comfortable, sweat absorption and porous.

Product Structure

Neonatal Phototherapy Protection Mask mainly consists of mask body and shield.

Intended Use

Neonatal Phototherapy Protection Mask are intended to protect the eyes during the phototherapy.









Operation Procedure

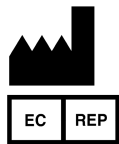
1. Select appropriate specification according to the head circumference of the patients.
Please do not pull the product hardly to prevent from damage.
2. Place eye shields over infant's eyes; assure infant has closed their eyes.
3. Remove eye shields at least every 8 hours; inspect eyes and replace prior to placing back under phototherapy lights.

Storage Conditions

5℃~40℃

Interpretation of Symbols

	CE MARK		Manufacturer
	European Authorized Representative		LOT Number
	Date of Manufacturing		Single Use Only
	Read Instructions before Use		Storage Conditions



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