Risk analysis report

Company	Ontecklong(Nanjing) Medical Supply Corporation Limited
Address	Bldg 10,Jinshangfang,No.288 South Xiongzhou Road, Liuhe District,Nanjing,210048 Jiangsu, P.R.China
Product	Neonatal Phototherapy Protection Mask
Accessories	N/A
Standard	EN ISO 14971:2009
Conclusion	It has been concluded through the process of risk analysis that this is a low risk device and any risks that existed were eliminated or reduced through safety testing, proper choice of materials and thorough instructions for use.

Edited by	Li Yun	Date:	9th June,2011
Reviewed	Li Nong	Date	9th June,2011
Approved by	Richard Yu	Date	9th June,2011

1. Devices features(According to EN ISO 14971:2009 Annex C）

No	Question	conclusion
1	Intended use and how to use	To protect neonatal baby's eyes during phototherapy treatment Cover the neonatal phototherapy protection mask on the baby's eyes with adhesive tape.
2	Intended to be implanted	N/A
3	Intended to contact patient or other person	Contact the surface of baby's skin
4	Materials/components used	Elastic physical bonding fabric, spunlaced non-woven cloth
5	Energy to/from patient	N/A
6	Substances to /from patient	N/A
7	Biological materials processed	N/A
8	Sterile/Intended to be sterilized	N/A
9	routinely cleaned and disinfected by the user	N/A
10	Intended to modify patient environment	N/A
11	Measurements	N/A
12	Interpretative	N/A
13	use in conjunction with medicines or other medical technologies	N/A
14	Unwanted outputs of energy or substances	N/A
15	Susceptible to environmental influences	Stored in dry environment
16	influence the environment	N/A
17	Consumables/accessories associated	N/A
18	Routine maintenance/calibration	N/A
19	Software	N/A
20	Restricted "shelf-life":	Three years
21	Delayed and/or long-term use effect	N/A

22	Mechanical forces	Friction between the patient and product
23	Lifetime of the device determined	Storage environment
24	Single use/re-use	Single use
25	safe decommissioning or disposal	N/A
26	Special training required to install or use	N/A
27	How to offer information for using safely	Instruction for use
28	new manufacturing processes need to be established or introduced	N/A
29	successful application of the medical device critically dependent on human factors, such as user interface	N/A
29.1	Design feature of User interface leads to use mistake	N/A
29.2	Using in wrong environment due to attention distraction	N/A
29.3	connecting parts or accessories	N/A
29.4	control interface	N/A
29.5	display information	N/A
29.6	controlled by a menu	N/A
29.7	Used by people with special need	N/A

2. Relative Standard

- EN ISO 13485:2003/AC2009 Medical devices - Quality management systems - Requirements for regulatory purposes
- 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 1041:2008 Information supplied by the manufacturer 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

3. Risk Evaluation

PROBABILITY OF OCCURRENCE	PROBABILITY RANGE	DESCRIPTION
FREQUENT	$\geq 10^{-3}$	OCCURRING OFTEN OR REPEATEDLY
PROBABLE	$< 10^{-3}$ and $\geq 10^{-4}$	REASONABLY LIKELY TO OCCUR
OCCASIONAL	$< 10^{-4}$ and $\geq 10^{-5}$	IRREGULAR OCCURRENCE, INFREQUENT
REMOTE	$< 10^{-5}$ and $\geq 10^{-6}$	NOT LIKELY TO OCCUR
IMPROBABLE	$< 10^{-6}$	UNLIKELY TO EVER OCCUR

SEVERITY	DESCRIPTION
CATASTROPHIC	RESULTS IN PATIENT DEATH
CRITICAL	RESULTS IN PERMANENT IMPAIRMENT OR LIFE-THREATENING INJURY
SERIOUS	RESULTS IN INJURY OR IMPAIRMENT REQUIRING PROFESSIONAL MEDICAL INTERVENTION
MINOR	LOW RISK FAILURE NOT EXPECTED TO CONTRIBUTE TO AN INJURY
NEGLIGIBLE	INSIGNIFICANT FAILURE NOT SERIOUS ENOUGH TO CONTRIBUTE TO AN INJURY

PROBABILITY OF OCCURRENCE	SEVERITY CATEGORIES				
	NEGLIGIBLE	MINOR	SERIOUS	CRITICAL	CATASTROPHIC
FREQUENT	14	7	5	3	1
PROBABLE	16	9	7	5	2
OCCASIONAL	18	12	9	6	4
REMOTE	19	15	13	11	8
IMPROBABLE	20	17	15	13	10

HAZARD RISK INDEX	ACCEPTANCE CRITERIA

1 TO 5	UNACCEPTABLE
6 TO 9	UNDESIRABLE. WRITTEN & REVIEWED DECISION TO PROCEED
10 TO 16	ACCEPTABLE UPON COMPLETION OF QUALITY ASSURANCE/REGULATORY REVIEW
17 TO 20	ACCEPTABLE WITHOUT REVIEW

4. Risk analysis

Potential Risk	Potential Reason	Risk Evaluation（ Before the risk controlling measure）			Measure to alleviate Risk	Response	Risk Evaluation（After the risk controlling measure）		
		Severity	Probability of occurrence	Risk			Severity	Probability of occurrence	Risk
Infection to patient	Too much bacterial	3	4	ALARP	Manufacturing environment controlling	Instruction for manufacturing Instruction for environment controlling	3	1	ACC
Infection to patient	Cross-infection due to repeated use	3	4	ALARP	Single use marked in the label and instruction for use	Label, Instruction for use	3	1	ACC
Stimulation to skin	Improper raw material	3	4	ALARP	Select the qualified raw material	List of raw material Testing report	3	1	ACC
Unable to block the blue light effectively	Improper raw material	3	4	ALARP	Select the qualified raw material	List of raw material Testing report	3	1	ACC
Damage to the product	Destroyed package	2	4	ALARP	Use qualified packing material	List of packing material Description of package	2	1	ACC
Damage to the product	Destroyed package	2	4	ALARP	Use qualified packing material	List of packing material Description of package	2	1	ACC

Potential Risk	Potential Reason	Risk Evaluation（ Before the risk controlling measure）			Measure to alleviate Risk	Response	Risk Evaluation（After the risk controlling measure）		
Unable to be used effectively	Improper instruction for use	3	4	ALARP	Complete and detailed Instruction for use shall include	Labeling, Instruction for use	3	1	ACC
Unable to be used effectively	Not used by professionals	3	4	ALARP	People who use this product shall have nursing ability and understand the instruction for use	Labeling, Instruction for use	3	1	ACC
Hurt to baby's skin	Sharp acute angle	2	4	ALARP	Use soft material and wit design	List of raw material Design	2	1	ACC
Damage to the product	Shed-off due to movement	3	4	ALARP	Heat-sealing quality and strength testing	Quality testing	3	1	ACC

5. Conclusion

It has been concluded through the process of risk analysis that this is a low risk device and any risks that existed were eliminated or reduced through safety testing, proper choice of materials and thorough instructions for use.