



Compliance Report

Applicant: Ontecklong (Nanjing) Medical Supply Corporation Limited.
Address: Bldg 5, No.2 Future Road, Park Zhongshan, Liuhe district
Nanjing, 210048 Jiangsu, P.R China.

Product: Neonatal Phototherapy Eye Mask,
Neonatal Phototherapy Diaper,
Neonatal Elastic Warm Cap,
Limb Board,
Newborn Nest

Type: See annex for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

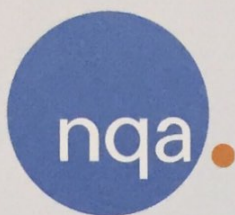
This report is not a certificate of conformity.

No. 02885

Initial Issue Date: 7 May 2018

Tony Chen

General Manager (Signature)



Annex to Report (No. 02885)

Ontecklong (Nanjing) Medical Supply Corporation Limited.

Product Name	Type
Neonatal Phototherapy Eye Mask	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
Neonatal Phototherapy Diaper	Neonatal Small, Neonatal Medium, Premature Small, Premature Medium, Premature Large
Neonatal Elastic Warm Cap	Small, Medium, Large
Limb Board	Small, Medium, Large
Newborn Nest	Small, Medium, Large

This annex is only valid if attached to the report mentioned above.