

CE Technical Documentation Review Report

Applicant: Ontecklong (Nanjing) Medical Supply Corporation Limited
Bldg 10, Jinhufang, No 288 South Xiongzhou Road,
Liuhe District Nannjing ,210048 Jiangsu, P.R.china

Report Number: 16801131.001

Examination intent: Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII

Product(s): See the attachment

Type(s)/Model(s): See the attachment

Classification: Class I
(according to manufacturer's declaration)

Examination period: May.03.2012

Date of expiry: May.02.2017

Review result: During the examination of the provided Technical Documentation (No.:CE/ATL-001, Revision: 1.0, dated 2011-06-29; No.:CE/ATL-002, Revision: 1.0, dated 2011-12-05; No.:CE/ATL-004, Revision: 1.0, dated 2011-12-02; No.:CE/ATL-006, Revision: 1.0, dated 2011-12-05), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd Beijing Operation



Chengyuhong

Yuhong CHEN
Manager (Beijing Operation)
Medical Services

Rev.01, 2002-10-10

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Attachment to
Report Number: 16801131.001

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Bldg 10, Jinhufang, No 288 South Xiongzhou Road, Liuhe District Nannjing ,210048 Jiangsu, P.R.china

Product(s): **Neonatal Phototherapy Protective Eye Masks** UMDNS Code: 11-659
Neonatal Phototherapy Protective Diapers UMDNS Code: 11-240
Neonatal Elastic Warm Caps UMDNS Code: 16-081
Arm-boards UMDNS Code: 15-735

Type(s)/Model(s): Neonatal Phototherapy Protection Masks:
Type I/ I-N/ II/ III/ IV/ V/ V-N/ VI/ VII Large, Medium, Small,
Extra Small

Neonatal Phototherapy Protection Diapers:
Neonatal/ Premature Medium, Small, Extra Small

Neonatal Phototherapy Protection Caps:
Small, Medium, Large

Arm-boards:
Small, Medium, Large

Examination period: May.03.2012

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Manager (Beijing Operation)
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