

2.3. 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

Richard Yu