



EC Declaration of Conformity

Manufacturer:

Name: Ontecklong(Nanjing) Medical Supply Corporation Limited
Address: Bldg 5, No.2 Future Road, Park Zhongshan, Liuhe district, Nanjing, China
Tel:86-25-51552233 Fax:86-25-84233533

EU Representative

Name: LiKing GmbH
Address: Fraunhofer Street 7,04178 Leipzig, Saxony, Germany
Tel:004934158096370

Product

Name: Neonatal Phototherapy Eye Mask
UMDNS-Code: 11659

Basic UDI-DI: 697472926ATL04NG

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

Classification: The medical device has been assigned to class I rule 1 according to Annex VIII of the Medical Device Regulation (EU) 2017/745.

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards.

EN ISO 13485:2016, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 15233-1:2016
EN ISO 10993-1:2020, EN 1041:2008, EN 62366-1:2015, EN ISO 14971:2012

Nanjing/24th May, 2023
Place, date

Richard Yu/General manager
Name/Position

Richard Yu

