



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
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Netherlands  
SRN: NL-AR-000000247

## Conformity Assessment

Conformity Assessment Procedure  
Annex II+III of Regulation (EU) 2017/745

### Applicable Standards

EN ISO 14971: 2019  
ISO 15223-1:2021/Amd 1:2025  
EN ISO 20417:2021  
EN ISO 10993-1: 2020  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2023  
EN ISO 10993-23: 2021

### Remark

*The declaration of conformity is valid in connection  
with the release technical document MDR-TCF-  
001*

*All the supporting documentation is retained at the  
premises of the manufacturer.*

*The Declaration of Conformity is exclusively under  
the sole responsibility of the manufacturer.*

File No.: MDR-TCF-001-08

Ver: A/0

## Manufacturer

**Name:** Ontecklong(Nanjing) Medical Supply Corporation  
Limited

**Address:** Bldg 5, No.2 Future Road, Park Zhongshan, Liuhe  
district, Nanjing, 210048 Jiangsu, P.R China

**SRN:** CN-MF-000047984

## Product Information

**Name:** Neonatal Phototherapy Eye Mask

**Model:** see annex

**EMDN:** V0299

**Basic UDI-DI:** see annex

**Classification:** Class I, According to Rule 1, Annex  
VIII, Regulation (EU) 2017/745

## Declaration

We herewith declare that the above-mentioned  
products meet the requirements of Medical Device  
Regulation (EU) 2017/745 and the applicable  
standards above.

Signature: *Richard Yu* Date: 2025/5/15

Position: GM

Place: Nanjing/China





## Annex

Product name	Model	Basic UDI
Neonatal Phototherapy Eye Mask	Type I Large	697472926NPEM01V2
	Type I Medium	
	Type I Small	
	Type II Large	697472926NPEM02V4
	Type II Medium	
	Type II Small	
	Type III Large	
	Type III Medium	
	Type III Small	
	Type IV Large	
	Type IV Medium	
	Type IV Small	
	Type IV-N Large	
	Type IV-N Medium	
	Type IV-N Small	
	Type VII Large	
	Type VII Medium	
	Type VII Small	
	Type V Medium	697472926NPEM03V6
	Type V Small	
	Type V-N Medium	
	Type V-N Small	