



EC Declaration of Conformity
Regarding Medical Device Directive (93/42 /EEC)
Including Directive (2007/47/EC)

Manufacturer:

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EC Representative:

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Product: Neonatal Phototherapy Eye Mask

Part numbers

1114015	NeoMask Neonatal Phototherapy Eye Mask – Large, Type III.	Pack of 20
1114016	NeoMask Neonatal Phototherapy Eye Mask – Medium, Type III.	Pack of 20
1114017	NeoMask Neonatal Phototherapy Eye Mask – Small, Type III.	Pack of 20

UMDNS-Code: 11-659

Classification: I

Rule: According to rule 1

We confirm our product can meet the requirement of Medical Device Directive and following harmonized standards:

EN ISO14971:2012
EN ISO 15223-1:2016
EN 1041:2008
EN ISO 10993-1:2009/AC2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013

Signature:

Richard Yu

Date: 2021.01.07

