

Declaration of Conformity


DOC-117 Rev A NeoShades

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Neotech Products LLC	28430 Witherspoon Pkwy Valencia CA 91355 USA	US-MF-000001895

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/fax/email
Emergo Europe	Westervoortsedijk 60 6827 AT, Arnhem, The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
NeoShades	N720, N721, N722, N724, N725, N726, N727, N728, N729	081259401N72000M5

Intended Purpose	Photo
The NeoShades are indicated for use as eye protection during phototherapy sessions. They are intended for use on pediatric (neonates, infants and children) patients.	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class <u>I</u> Rule <u>1</u> + Category II PPE Directive Non-Invasive device. Only contact with intact skin. Other rules are not applicable.	N/A

NOTIFIED BODY			
Name of Company	ID Number	Conformity Assessment Procedure	Certificate Reference(s)
BSI	Notified Body 2797	Neotech Products LLC declares that the above-mentioned products meet the provision of the Annex II of legislation (EU) 2016/425 of 9 March 2016 on the personal protective equipment	CE 693481

Neotech Products LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745
- PPE (EU) 2016/425

COMPANY REPRESENTATIVE:

Leo Arya

Director of QA/RA

Signed by:
Leo Arya
Signer Name: Leo Arya
Signing Reason: I approve this document
Signing Time: 09/15/2025 | 12:07:07 PM PDT
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Valencia, CA, USA