

EU Declaration of Conformity

Manufacturer: Neotech Products LLC
28430 Witherspoon Parkway
Valencia, CA 91355

Certificate Number: CE 693481

Authorized EC Representative: Emergo Group
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Notified Body: BSI Group (0086), Kitemark Court, Davy Avenue
Knowlhill, Milton Keynes MKS 8PP,
United Kingdom

Reference number for Notified Body 0086

Manufacturing Facility: Manufacturing Site: same as above


Product Model Number:	Model No.	Description	Size
	N720	Neoshades with Tabs	Micro
	N721	Neoshades with Tabs	Small
	N722	Neoshades with Tabs	Large
	N724	Neoshades with Tabs/Ocular Pocket	Micro
	N725	Neoshades with Tabs/Ocular Pocket	Small
	N726	Neoshades with Tabs/Ocular Pocket	Large
	N727	NeoShades with Headstrap/Ocular Pocket	Micro
	N728	NeoShades with Headstrap/Ocular Pocket	Small
	N729	NeoShades with Headstrap/Ocular Pocket	Large

Product Model Description: Photo therapy Eye Shields

Classification: MDD 93/42/EEC Class I Medical Device (Rule1) + Category II PPE Directive

Conformity Assessment Route: Essential Health & Safety Requirements of the PPE Regulation (EU) 2016/425 and Annex VII of MDD 93/42/EEC Directive.

I, the undersigned, hereby declare and authorize to certify that the Medical Device(s) specified above meet(s) the provisions of the Essential Health & Safety Requirements of the PPE Regulation (EU) 2016/425 which apply to them, as transposed into the national laws of the EU member states. In addition, we declare that our product meets the provisions as laid out under Annex II of (EU) 2016/425 of Essential Safety Requirements and Annex VII of MDD 93/42/EEC of EC Declaration of Conformity as a self-certified non-sterile non-measurement Medical Device(s).

Print Name: Leo Arya
Place: Valencia, CA
Signature: 

Title: QA, RA Manager
Date: 12.28.18