

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 (2797),**
Say Building, John M. Keynesplein 9
1066 EP Amsterdam, Netherlands

Manufacturing Facility: **Reference number for Notified Body 2797**
Product Model Number: **Manufacturing Site: same as above**

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

Title: Quality Assurance & Regulatory Affairs Manager

Place: Valencia, CA

Date: 12/23/2019

Signature:

