

EU Type Examination Certificate

This is to certify that:

Neotech Products LLC
28430 Witherspoon Parkway
Valencia
California
91355
USA

Holds Certificate Number:

CE 693481

In respect of:

NeoShades eye protectors
Technical specification to Annex II of the PPE Regulation (EU) 2016/425

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Denelise L'Ecluse, Managing Director Assurance - Continental Europe

First Issued: 2018-12-04

Latest Issue: 2023-05-22

Effective Date: 2023-05-22

Expiry Date: 2028-12-03

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No. CE 693481

Product specification

The eye and face protective products covered by the scope of this Module B Certificate and the technical specification to which the products are approved are to the following specifications:

Product type: NeoShades eye protectors

Description: The NeoShades eye protectors are for use under phototherapy lights or applications where there is a need for the protection of paediatrics (neonates, infants and children) eyes from exposure to elevated levels of light.

Technical Specification: Technical specification to Annex II of the PPE Regulation (EU) 2016/425

Models and classification:

Model	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

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Certificate Administration Details

Technical File Reference: TF N720 NeoShades, PPE Regulation (EU) 2016/425

Issue date	Comments	BSI Review Ref.
May 2023	Certificate 5-yr Renewal; update Notified Body number to 2797	2797:23:3911954
November 2018	First issue.	0086:18:8940371

Note: The Certificate holder is responsible for keeping the Notified Body advised of changes to any aspect of the overall process used in the manufacture of the product.

Monitoring of manufactured PPE

The Conformity to Type Based on internal production control, Annex VI (Module C).
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