

BL-100-BL Blue Blade **Lead Glasses**

Certificate GB06/68668, continued

SGS

Pulse Medical Inc.

EC Council Directive 89/686/EEC

EC Type-examination
Issue 1.



PPE Product

- a) Pulse Medical "Maxi" frames fitted with X-ray radiation filtering lenses (plano lead glass) and attached lead side shields, which are available in four frame colour options: Blue (style code: MAX-100S-BL), Silver (MAX-100S-S), Black (MAX-100S-BK) and Crimson (MAX-100S-R).
- b) Pulse Medical "Pulse Lite" frames fitted with X-ray radiation filtering lenses (plano lead glass) and attached lead side shields, which are available in five frame colour options: Bronze (style code: PL-100S-BR), Silver (PL-100S-S), Black (PL-100S-BK), Crimson (PL-100S-CR) and Satin Grey Blue (PL-100S-GB).
- c) Pulse Medical "Icicles" frames fitted with X-ray radiation filtering lenses (plano lead glass) and attached lead side shields, which are available in two frame colour options: Blue (style code: IC-100S-BL) & Orange (IC-100S-O).

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to be in accordance with the requirements of Council Directive 89/686/EEC. When examined the PPE satisfied the relevant requirements in the manufacturer's technical specification¹ (based on EN 61331-1:2002 test requirements), which had been previously assessed and deemed to meet the basic health and safety requirements (Annex II) of the Directive. The nominal lead equivalences were 0.75mm Pb for the lenses and 0.35mm Pb for the side shields.

The manufacturer's information notice (Radiation Filtering Glasses) in English has been inspected and found to have addressed all of the relevant requirements of the Directive (Annex II, 1.4). However, the detailed content of the information notice is the responsibility of the manufacturer, as are translations into other languages.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 11 of the Directive are implemented and maintained while the model is in production.

Certification is based on technical file "Pulse Medical Inc."
SGS Reference Number GB/PP 214085.

¹ The validity of this certificate may have to be reviewed in the light of new or amended harmonized standards.