

## **CE Certificate of Conformity**

We Euro Optics bv

declare under our sole responsibility that

- Reading glasses collection InFocus// Medical Device class 1

to which this declaration relates is in conformity with the following standard

Regulation: (EU) 2016/425 (of the European parliament and of the council of 9 March 2016) on personal protective equipment and repealing council Directive 89/686/EEG

The following normative standards has been applied.

EN ISO 14139:2010 (Ophthalmic optics – specifications for ready to wear spectacles June 2010)

EN ISO (EU) 2017/745 (on Medical devices of 5 April 2017)

ISO16034:2002(E)

Ophthalmic optics – Specifications for single-vision ready-to-wear near-vision spectacles

And regarded as being nickel free ie. a nickel emission less then the allowed percentage.

Class 1 medical devices are devices with low or moderate risk to patient health and safety. 47% of approved medical devices are Class 1, and 95% of these devices are exempt from the PMA pathway to regulatory approval



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