

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

if applicable:

ISO16034:2002(E)

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

NEN-EN 14139:2010

EN 14139:2010

EN ISO 12312:1:2013

Ophthalmic optics – Specifications for ready-made eyeglasses

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

and therefore complies with the requirements of Council Directive Medical Devices 93/42/EEC and 76/769/EEG included 94/27/EEG

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



Euro Optics bv