

EU Declaration of Conformity

Firma: HVEG Accessoires Groep Meerenakkerweg 10 5652AT Eindhoven Nederland,

Product description: Ready to wear spectacles / reading glasses - Medical Device Risk Class I Product code: RDR03225-003, RDR03683-006, RDR03730-001, RDR03729-000, RDR03693-005, RDR03196-001

Product UDI: 006-230608

We declare under sole responsibility that the medical device mentioned above conforms with the applicable provisions of REACH Regulation (EC) No 1907/2006 and (MDR) Medical Device Regulation (EU) 2017/745, as well as with the following standard in its most recent release: EN 14139 Ophthalmic optics – Specifications for ready-to-wear spectacles

And therefore with

EN ISO 8980-1	Ophthalmic optics - Uncut finished spectacle lenses - Part 1: Specifications for single-vision and multifocal lenses
EN ISO 12870	Ophthalmic optics - Spectacle frames - Requirements and test methods
EN ISO 14889	Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses
EN 16128	Reference test method for release of nickel from those parts of spectacle frames and sunglasses intended to come into close and prolonged contact with the skin

Remarks:

All materials of the objects described above comply with REACH regulation. A proof can be provided that all materials, that have skin contact, are biocompatible.

The ready-to-wear spectacles have been tested according EN 14139 and have completely met the requirements.

The lenses fulfil the optical requirements of EN 14139 / EN ISO 8980-1 not only in the optical centre, but also within a radius of 1 cm around the optical centre. This has been verified by checking at 5 measuring points (optical centre + 1 cm above, below, left, right of the optical centre).

Signed for and on behalf of HVEG Accessories Group

Eindhoven, 13 November 2023 Kwaliteitsmanager, Nora Chorfi

