

EU Declaration of Conformity

Product name: Compact 8
Product model: CP8
Basic UDI-DI: 0850017300CP8UU
Product Reference: CP8-UMME
CP8-UMUK
Product Risk Class: Class I (rule 1 & 13, Medical Device Regulation, Annex VIII)
Intended purpose: Vision Enhancement Aid

The product described on this declaration is in conformity with:

Name	Version/Document number
Medical Device Regulation	2017/745
Radio Equipment Directive	2014/53/EU
Waste from Electrical and Electronic Equipment (WEEE) Directive	2012/19/EU
restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS)	2011/65/EU

Manufacturer:

Optelec Nederland B.V.
Pesetastraat 5^a
2991 XT Barendrecht
The Netherlands

SRN: NL-MF-000027675

Conformity assessment procedure: Art. 52(7) & Annex II, III & IV, Medical Device Regulation.

I, the undersigned, hereby declare that this declaration is issued under the sole responsibility of the Manufacturer, and that the equipment specified herein conforms to the above Directive(s) and Regulation(s).

Name: B.J.M. KOFFLAARD

Title: MANAGING DIRECTOR

Signature: [Signature]

Date: 21 APRIL 2023

Place of Issue: BARENDRICHT

Date Issued: March 23, 2023