



EU DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

Manufacturer:	MelaMedic ApS Stenildhøjvej 34 B DK-9600 Aars Denmark Tel.: +45 2195 3322 Mail: info@melamedic.dk Web: www.melamedic.dk
Product(s):	Circadian eyewear – Blue-Blocking Sleep Glasses UV530
MDR classification:	Medical Device class 1, for therapeutical use.
Indication for use:	<p>The essential performance of the sleeping glasses with the special designed medical blue light blocking glasses (UV530 lenses) are to control the melatonin-cycle to improve sleeping and stabilize free accessible serotonin in the body during the daytime.</p> <p>The use of the sleeping glasses invokes the production and secretion of the important signaling substance melatonin from the pineal gland in the brain, which i.a. stimulates sleep, sleep quality and other physiological symptoms.</p>
Intended use:	<p>The sleeping glasses are intended for the prevention and relief of sleep problems and jet lag when used in the home environment. Furthermore, correction of shifted sleep patterns. Not for use while driving a car.</p> <p>Additionally, the effect of stimulating the melatonin production by use of the sleeping glasses also seems to help on other physiological symptoms.</p>
Model(s), Type, EAN:	<p>Amsterdam II SKU: MM-011 EAN 575711669000113</p> <p>Berlin SKU: MM-004 EAN: 5711669000045</p> <p>Bern II SKU: MM-311 EAN: 5711669003114</p> <p>Bern III SKU: MM-041 EAN: 5711669000410</p> <p>Brussels SKU: MM-022 EAN: 5711669000229</p> <p>Copenhagen II (For children age 6-10 years) SKU: MM-037 EAN: 5711669000373</p>

Copenhagen III (For children age 6-11 years)

SKU: MM-012

EAN: 5711669000120

Dublin (Fitover, on top of existing glasses)

SKU: MM-001

EAN: 5711669000014

London (Fit over, on top of existing glasses)

SKU: MM-002

EAN: 5711669000021

Rome

SKU: MM-005

EAN: 5711669000052

Vienna

SKU: MM-250

EAN: 5711669002506

The Manufacturer declares under its sole responsibility that the listed sleeping glass model(s) are in conformity with the essential requirements and other relevant requirements of the following Directives and Regulations:

The Medical Devices Regulation 2017/745/EU for medical class 1 products and the PPE Regulation 2016/425/EU, Annex II with applied standards for sunglasses with the purpose for Blue-blocking Sleep Glasses UV530.

Standard(s) Applied in Full:

EN ISO 12312-1:2013+A1:2015

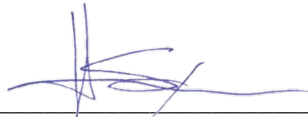
Eye and face protection – Sunglasses and related Eyewear Part 1: Sunglasses for general use

The following conditions apply for the UV530 Sleeping Glass:

1. *The UV530 sleeping glass is not a protective eye wear.*
2. *The UV530 sleeping glass is not a standard sunglass as blue light is fully blocked.*

Testing performed by Taiwan Spectacles Industry Association, 2nd Fl. No. 206, Sec 2 Min-Chuan E. Road, Taipei, Taiwan R.O.C. and PPE Regulation/MDR Regulation conformity assessment by MelaMedic Aps.

Signed on behalf of MelaMedic Aps, 2024-04-28.



Henrik Sørensen

Product Development Manager

