

EC Declaration of Conformity



Manufacturers Name: Bloomdale Eyewear

Manufacturers Address: Kievitsven 80
5249 JK Rosmalen
THE NETHERLANDS
Tel. +31 736990021

SRN (Single Registration Number): NL-MF-000040573

Authorized Representative Name: Not applicable

Basic UDI-DI/ GMN: 872087289

Name of the Device (s): Spectacle Frames

Product code: Product BD746*

Classification: MDR class I

Notified Body name: Not applicable

Notified Body Identification number: Not applicable

Conformity assessment route: Bloomdale Eyewear BV uses the following procedures for the CE-labelling of their products according to the Regulation MDR 2017/745: Class I: EC conformity declaration according to MDR, *Annex II, III, IV, Rule 1*

This declaration of conformity is issued under the sole responsibility of Bloomdale Eyewear BV. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.



The product carries the CE mark:

This declaration is supported by the Quality Management System approval and compliance of the organization with the ISO 13485:2016 certificate, which certificate is issued by LRQA. All supporting documentation is retained at the premises of the legal manufacturer.

Signature:

Armand van Lingen General Manager
Bloomdale Eyewear BV

Place and date of issue:

Rosmalen, January 2024



Bloomdale Eyewear
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K.v.K. nr. 599998873
VAT. NL853725457B01

- Following collections will obtain a specific BD number and UDI, we will inform you per collection, with the four to six colour per model.

Technical File Bloomdale Eyewear BV	Page 1 of 8
Chapter 1.1.10 DoC 2024	Date: 20-03-2023

Annex 1

BD 501 col. 30	BD 508 col. 80	BD 517 col. 65	BD 526 col. 45
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Technical File Bloomdale Eyewear BV	Page 8 of 8
Chapter 1.1.10 DoC 2024	Date: 20-03-2023