



EC Declaration of Conformity

Manufacturers Name: Dutz Eyewear BV

Manufacturers Address: Dutz Eyewear BV
Angelenweg 162, 5349 TC Oss
THE NETHERLANDS
Tel. +31 412 645 000

SRN (Single Registration Number): NL-MF-000036610

Basic UDI-DI/ GMN: 8719059DZ.DT.DS.DK.YH

GMDN: 32816 – Frame, spectacle

EMND: Q02100201 – Metal spectacle frames without lenses
Q02100202 – Plastic spectacle frames without lenses
Q02100203 – Metal and plastic spectacle frames without lenses

Name of the Device (s): Spectacle Frames for Ophthalmic Lenses

Product code: See pages 2, 3, 4 & 5 of this DoC

Classification: MDR class I

Notified Body name: Not applicable

Conformity assessment route: Dutz 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 Dutz 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:



Place and date of issue:

Oss, January 25, 2024

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Arianne Jonkergouw
Dutz Eyewear BV
Quality Assurance/ Design & Development

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Types/ Models and colour of Spectacle Frames for Ophthalmic Lenses

Name of the Device (s):	Colour-code and design collection code	GTIN
Dutz sunglasses	DS013-25	8719059037173
	DS013-46	8719059037180
	DS013-75	8719059037197
	DS014-45	8719059037203
	DS014-76	8719059037210
	DS014-85	8719059037227
	DS015-46	8719059037234
	DS015-75	8719059037241
	DS015-76	8719059037258
	DS016-45	8719059037265
	DS016-46	8719059037272
	DS016-75	8719059037289
	DS017-35	8719059037296
	DS017-46	8719059037302
	DS017-95	8719059037319
	DS018-45	8719059037326
	DS018-47	8719059037333
	DS018-55	8719059037340
	DS019-45	8719059037357
	DS019-46	8719059037364
Dutz collection acetate & combination frames	DS019-85	8719059037371
	DS020-15	8719059037388
	DS020-65	8719059037395
	DS020-76	8719059037401
	DZ2312-35	8719059037906
	DZ2312-45	8719059037913
	DZ2312-75	8719059037920
	DZ2312-76	8719059037937
	DZ2313-45	8719059037944
	DZ2313-55	8719059037951
	DZ2313-65	8719059037968
	DZ2313-76	8719059037975
	DZ2314-46	8719059037982
	DZ2314-65	8719059037999
	DZ2314-75	8719059038002
	DZ2314-76	8719059038019
	DZ2315-45	8719059038026
	DZ2315-46	8719059038033
	DZ2315-65	8719059038040
	DZ2315-75	8719059038057
DZ2316-45	8719059038064	
DZ2316-55	8719059038071	
DZ2316-65	8719059038088	
DZ2316-85	8719059038095	
DZ2316-95	8719059038101	
DZ2317-45	8719059038118	
DZ2317-46	8719059038125	
DZ2317-65	8719059038132	
DZ2317-76	8719059038149	
DZ2318-45	8719059038156	
DZ2318-46	8719059038163	
DZ2318-47	8719059038170	
DZ2318-85	8719059038187	



	DZ2319-45 DZ2319-46 DZ2319-76 DZ2319-85 DZ2320-15 DZ2320-65 DZ2320-76 DZ2320-95 DZ2321-45 DZ2321-47 DZ2321-85 DZ2322-15 DZ2322-45 DZ2322-65 DZ2322-95 DZ2323-45 DZ2323-46 DZ2323-65 DZ2323-76 DZ2324-45 DZ2324-46 DZ2324-55 DZ2324-75 DZ2325-45 DZ2325-46 DZ2325-55 DZ2325-65 DZ2326-65 DZ2326-75 DZ2326-76 DZ2326-85 DZ2327-45 DZ2327-46 DZ2327-55 DZ2327-85 DZ2328-35 DZ2328-46 DZ2328-55 DZ2328-85 DZ2329-45 DZ2329-46 DZ2329-65 DZ2329-76 DZ2330-46 DZ2330-76 DZ2330-85 DZ2330-95 DZ2331-25 DZ2331-45 DZ2331-46 DZ2331-76 DZ2332-35 DZ2332-45 DZ2332-55 DZ2332-76	8719059038194 8719059038200 8719059038217 8719059038224 8719059038231 8719059038248 8719059038255 8719059038262 8719059038279 8719059038286 8719059038293 8719059036497 8719059036503 8719059036510 8719059036527 8719059036534 8719059036541 8719059036558 8719059036565 8719059036572 8719059036589 8719059036596 8719059036602 8719059036619 8719059036626 8719059036633 8719059036640 8719059036657 8719059036664 8719059036671 8719059036688 8719059036695 8719059036701 8719059036718 8719059036725 8719059036732 8719059036749 8719059036756 8719059036763 8719059036770 8719059036787 8719059036794 8719059036800 8719059036817 8719059036824 8719059036831 8719059036848 8719059036855 8719059036862 8719059036879 8719059036893 8719059036909 8719059036916 8719059036923 8719059036930
Dutz collection metal frames	DZ852-45 DZ852-65 DZ852-75 DZ852-76 DZ853-15 DZ853-46	8719059038453 8719059038460 8719059038477 8719059038484 8719059038415 8719059038422



DZ853-65	8719059038439
DZ853-75	8719059038446
DZ853-76	8719059038378
DZ854-45	8719059038385
DZ854-65	8719059038392
DZ854-75	8719059038408
DZ854-76	8719059038330
DZ854-77	8719059038347
DZ855-25	8719059038354
DZ855-45	8719059038361
DZ855-46	8719059037852
DZ855-55	8719059037869
DZ855-65	8719059037876
DZ856-10	8719059037883
DZ856-45	8719059037890
DZ856-55	8719059037814
DZ856-65	8719059037821
DZ857-35	8719059037838
DZ857-45	8719059037845
DZ857-46	8719059037777
DZ857-55	8719059037784
DZ857-95	8719059037791
DZ858-35	8719059037807
DZ858-45	8719059037722
DZ858-47	8719059037739
DZ858-85	8719059037746
DZ858-95	8719059037753
DZ859-35	8719059037760
DZ859-45	8719059035964
DZ859-46	8719059035971
DZ859-47	8719059035988
DZ859-55	8719059035995
DZ860-45	8719059036251
DZ860-47	8719059036268
DZ860-85	8719059036275
DZ860-95	8719059036282
DZ861-45	8719059036213
DZ861-65	8719059036220
DZ861-85	8719059036237
DZ861-95	8719059036244
DZ862-45	8719059036336
DZ862-55	8719059036343
DZ862-65	8719059036350
DZ862-85	8719059036367
DZ863-45	8719059036374
DZ863-47	8719059037685
DZ863-65	8719059036299
DZ863-76	8719059036305
DZ863-95	8719059036312
DZ864-45	8719059036329
DZ864-46	8719059037715
DZ864-55	8719059036176
DZ864-95	8719059036183
DZ865-35	8719059036190
DZ865-45	8719059036206
DZ865-65	8719059036138
DZ865-85	8719059036145
DZ866-15	8719059036152
DZ866-45	8719059036169
DZ866-46	8719059036084
DZ866-65	8719059036091



	DZ866-75 DZ867-45 DZ867-46 DZ867-55 DZ867-76 DZ868-45 DZ868-46 DZ868-65 DZ868-75 DZ869-35 DZ869-45 DZ869-46 DZ869-76 DZ870-45 DZ870-65 DZ870-85 DZ870-95	8719059036107 8719059036114 8719059036121 8719059035872 8719059035889 8719059035896 8719059035902 8719059035919 8719059035926 8719059035933 8719059035940 8719059035957 8719059038491 8719059036046 8719059036053 8719059036060 8719059036077
Dutz collection titanium frames	DT017-45 DT017-46 DT017-95 DT018-45 DT018-85 DT018-95 DT019-45 DT019-46 DT019-76 DT020-45 DT020-46 DT020-85	8719059036978 8719059036985 8719059036992 8719059037005 8719059037012 8719059037029 8719059037609 8719059037616 8719059037623 8719059037630 8719059037647 8719059037654

Intended use: intended to be used with ophthalmic lenses to correct vision in eyeglasses.

The DoC consists of a product family of frames, with 4 or 5 colours for DZ frames and 3 colours for DT and DS frames. For every batch, a product code and identifier (UDI) will be affixed to assure traceability.

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