



EU DECLARATION OF CONFORMITY

DI ESSE S.r.l, located in Via Vittorio Veneto 1, località Vallesella, Domegge di Cadore, (BL), Italia;
in its capacity as the manufacturer, under its sole responsibility, hereby

declares

that the spectacle frames, in all its versions (colors and sizes)

CODE	DESCRIPTION	BASIC UDI-DI
CJ1475V005500001	SMS305 55-17-135 1 MET.FRAMES	805759259 MET RU
CJ1475V005500002	SMS305 55-17-135 2 MET.FRAMES	805759259 MET RU
CJ1475V005500003	SMS305 55-17-135 3 MET.FRAMES	805759259 MET RU
CJ1480V005300190	SMS306 53-16-135 190 PLS.FRAMES	805759259 ACE NU
CS5416V005300190	SMS314 53-17-140 190 PLS.FRAMES	805759259 ACE NU
CS5416V005300500	SMS314 53-17-140 500 PLS.FRAMES	805759259 ACE NU
CS5422V005300001	SMS313 53-17-135 1 MET.FRAMES	805759259 MET RU
CS5422V005300002	SMS313 53-17-135 2 MET.FRAMES	805759259 MET RU
CS5422V005300003	SMS313 53-17-135 3 MET.FRAMES	805759259 MET RU
CS5427V005400190	SMS310 54-16-135 190 PLS.FRAMES	805759259 ACE NU
CS5429V005300001	SMS307 53-16-135 1 MET.FRAMES	805759259 MET RU
CS5429V005300001	SMS307 53-16-135 1 MET.FRAMES	805759259 MET RU
CS5429V005300003	SMS307 53-16-135 3 MET.FRAMES	805759259 MET RU
CS5429V005300003	SMS307 53-16-135 3 MET.FRAMES	805759259 MET RU
CS5430V005400001	SMS309 54-16-135 1 MET.FRAMES	805759259 MET RU
CS5430V005400005	SMS309 54-16-135 5 MET.FRAMES	805759259 MET RU
CS5430V005400008	SMS309 54-16-135 8 MET.FRAMES	805759259 MET RU
CS5445V005300090	SMS311 53-17-140 90 MET.FRAMES	805759259 MET RU
CS5445V005300095	SMS311 53-17-140 95 MET.FRAMES	805759259 MET RU
CS5446V005400080	SMS312 54-17-140 80 MET.FRAMES	805759259 MET RU
CS5446V005400080	SMS312 54-17-140 80 MET.FRAMES	805759259 MET RU
CS5446V005400092	SMS312 54-17-140 92 MET.FRAMES	805759259 MET RU
CS5446V005400092	SMS312 54-17-140 92 MET.FRAMES	805759259 MET RU
CS5468V005300097	SMS317 53-19-140 97 MET.FRAMES	805759259 MET RU
CS5493V005100002	SMS318 51-19-140 2 MET.FRAMES	805759259 MET RU



CS5493V005100080	SMS318 51-19-140 80 MET.FRAMES	805759259 MET RU
CS5493V005100085	SMS318 51-19-140 85 MET.FRAMES	805759259 MET RU
CS5496V005200002	SMS319 52-19-140 2 MET.FRAMES	805759259 MET RU
PE6005V005500019	SMS320 55-18-145 19 MET.FRAMES	805759259 MET RU
PE6005V005500090	SMS320 55-18-145 90 MET.FRAMES	805759259 MET RU
PE6005V005500095	SMS320 55-18-145 95 MET.FRAMES	805759259 MET RU

EUDAMED: SRN IT-MF-000036624

are a class 1 medical device (Rule 1 Chapter III of Annex VIII of (EU) Regulation 2017/745), which is intended for use in connection with, in the manufacturing of eyeglasses, ophthalmic lenses for correcting vision problems.

Also declares that it is in conformity with the provisions of (EU) Regulation 2017/745 on Medical Devices and with the standard EN ISO 12870:2018

DOMEGGE DI CADORE, date: 01/06/2024

ADMINISTRATOR,
Antonio De Silvestro.

DIESS
DIESS S.R.L. Via Vittorio Veneto 1, Fraz. Vallesella
32040 Domegge di Cad. (BL) - ITALY - C.F. 0115643326257
Tel. +39 0435.520134 - Fax +39 0435.728101



EU DECLARATION OF CONFORMITY

DI ESSE S.r.l, located in Via Vittorio Veneto 1, località Vallesella, Domegge di Cadore, (BL), Italia;
in its capacity as the manufacturer, under its sole responsibility, hereby

declares

that the spectacle frames, in all its versions (colors and sizes)

CODE	DESCRIPTION	BASIC UDI-DI
CS5532V005300340	SMS321 53-16-140 340 PLS.FRAMES	805759259 ACE NU
CS5534V005200190	SMS322 52-16-140 190 PLS.FRAMES	805759259 ACE NU
CS5536V005300100	SMS323 53-17-140 100 PLS.FRAMES	805759259 ACE NU
CS5536V005300190	SMS323 53-17-140 190 PLS.FRAMES	805759259 ACE NU
CS5585V005400019	SMS324 54-17-140 19 MET.FRAMES	805759259 MET RU
CS5585V005400095	SMS324 54-17-140 95 MET.FRAMES	805759259 MET RU
CS5591V005400001	SMS325 54-19-140 1 MET.FRAMES	805759259 MET RU
CS5591V005400002	SMS325 54-19-140 2 MET.FRAMES	805759259 MET RU
CS5593V005300019	SMS326 53-17-140 19 MET.FRAMES	805759259 MET RU
CS5593V005300090	SMS326 53-17-140 90 MET.FRAMES	805759259 MET RU
PE6050V005400076	SMS329 54-18-140 76 MET.FRAMES	805759259 MET RU
PE6050V005400092	SMS329 54-18-140 92 MET.FRAMES	805759259 MET RU
PE6050V005400096	SMS329 54-18-140 96 MET.FRAMES	805759259 MET RU

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Also declares that it is in conformity with the provisions of (EU) Regulation 2017/745 on Medical Devices and with the standard EN ISO 12870:2018

DOMEGGE DI CADORE, date: 01/12/2024

ADMINISTRATOR,
Antonio De Silvestro.

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DIESS S.R.L. Via Vittorio Veneto 1, Fraz. Vallesella
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A handwritten signature in blue ink is written over the printed text of the stamp.



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DI ESSE S.r.l., located in Via Vittorio Veneto 1, località Vallesella, Domegge di Cadore, (BL), Italia;

in its capacity as the manufacturer, under its sole responsibility, hereby

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CODE	DESCRIPTION	BASIC UDI-DI
CJ1559V005500001	SMS332 55-17-140 1 MET.FRAMES	805759259 MET RU
CJ1563V005400002	SMS333 54-16-135 2 MET.FRAMES	805759259 MET RU
CJ1563V005400003	SMS333 54-16-135 3 MET.FRAMES	805759259 MET RU
CJ1565V005400192	SMS334 54-16-140 192 PLS.FRAMES	805759259 ACE NU
CJ1565V005400502	SMS334 54-16-140 502 PLS.FRAMES	805759259 ACE NU
CS5508V005300001	SMS335 53-20-145 1 MET.FRAMES	805759259 MET RU
CS5508V005300019	SMS335 53-20-145 19 MET.FRAMES	805759259 MET RU
CS5508V005300080	SMS335 53-20-145 80 MET.FRAMES	805759259 MET RU
CS5532V005300360	SMS321 53-16-140 360 PLS.FRAMES	805759259 ACE NU
CS5534V005200100	SMS322 52-16-140 100 PLS.FRAMES	805759259 ACE NU
CS5593V005300019	SMS326 53-17-140 19 MET.FRAMES	805759259 MET RU
CS5593V005300090	SMS326 53-17-140 90 MET.FRAMES	805759259 MET RU
CS5600V005400190	SMS338 54-17-145 190 PLS.FRAMES	805759259 ACE NU
CS5600V005400705	SMS338 54-17-145 705 PLS.FRAMES	805759259 ACE NU
CS5612V005400001	SMS339 54-16-140 1 MET.FRAMES	805759259 MET RU
CS5612V005400002	SMS339 54-16-140 2 MET.FRAMES	805759259 MET RU
CS5637V005700001	SMS341 57-17-145 1 MET.FRAMES	805759259 MET RU
CS5637V005700002	SMS341 57-17-145 2 MET.FRAMES	805759259 MET RU
CS5637V005700003	SMS341 57-17-145 3 MET.FRAMES	805759259 MET RU
CS5656V005300096	SMS342 53-17-140 96 MET.FRAMES	805759259 MET RU
CS5679V005200190	SMS343 52-17-145 190 PLS.FRAMES	805759259 ACE NU
CS5679V005200350	SMS343 52-17-145 350 PLS.FRAMES	805759259 ACE NU
PE6086V005300070	SMS344 53-16-140 70 MET.FRAMES	805759259 MET RU
PE6086V005300090	SMS344 53-16-140 90 MET.FRAMES	805759259 MET RU



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are a class 1 medical device (Rule 1 Chapter III of Annex VIII of (EU) Regulation 2017/745), which is intended for use in connection with, in the manufacturing of eyeglasses, ophthalmic lenses for correcting vision problems.

conforms with Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH);

Also declares that it is in conformity with the provisions of (EU) Regulation 2017/745 on Medical Devices and with the standard EN ISO 12870:2018

DOMEGGE DI CADORE, date: 01/06/2025

ADMINISTRATOR,
Antonio De Silvestro.

DIESS
DIESS S.R.L. Via Vittorio Veneto 1, Fraz. Vallesella
32040 Domegge di Cad. (BL) - ITALY - C.F. e P.IVA IT 016133260257
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EU DECLARATION OF CONFORMITY

DI ESSE S.r.l., located in Via Vittorio Veneto 1, località Vallesella, Domegge di Cadore, (BL), Italia;

in its capacity as the manufacturer, under its sole responsibility, hereby

declares

that the spectacle frames, in all its versions (colors and sizes)

CODE	DESCRIPTION	BASIC UDI-DI
CJ1534V005400190	SMS330 54-17-140 190 PLS.FRAMES	805759259 ACE NU
CJ1534V005400550	SMS330 54-17-140 550 PLS.FRAMES	805759259 ACE NU
CJ1542V005400190	SMS331 54-16-140 190 PLS.FRAMES	805759259 ACE NU
CS5201V005300004	SMS275 53-17-140 4 MET.FRAMES	805759259 MET RU
CS5201V005300005	SMS275 53-17-140 5 MET.FRAMES	805759259 MET RU
CS5201V005300006	SMS275 53-17-140 6 MET.FRAMES	805759259 MET RU
CS5530V005300190	SMS336 53-16-140 190 PLS.FRAMES	805759259 ACE NU
CS5532V005300340	SMS337 53-16-140 340 PLS.FRAMES	805759259 ACE NU

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conforms with Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH);

Also declares that it is in conformity with the provisions of (EU) Regulation 2017/745 on Medical Devices and with the standard EN ISO 12870:2018

DOMEGGE DI CADORE, date: 06/10/2025

ADMINISTRATOR,
Antonio De Silvestro.

DIESE
DI ESSE S.R.L. Via Vittorio Veneto 1, Fraz. Vallesella
32040 Domegge di Cadore (BL) - ITALY - C.F. 01154130257
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EU DECLARATION OF CONFORMITY

DI ESSE S.r.l., with registered office in Domegge di Cadore (BL), via Vittorio Veneto 1, location Domegge di Cadore, Italy, as manufacturer and under our sole responsibility hereby

declares

that the spectacle frames, in all its versions (colors and sizes)

PC1039V005500190	SMS316 55-15-140 190 PLS.FRAMES + 2 SUN CLIPS	805759259 ACE NU
PC1039V005500750	SMS316 55-15-140 750 PLS.FRAMES + 2 SUN CLIPS	805759259 ACE NU
PC1039V005500800	SMS316 55-15-140 800 PLS.FRAMES + 2 SUN CLIPS	805759259 ACE NU

are medical device complies with the provisions of Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) when combined with a magnetic clip-on.

The device complies with the following harmonized standards:

- EN ISO 12870:2018
- EN ISO 12312-1:2022

Conformity has been assessed according to the applicable procedures set forth in the aforementioned regulations.

DOMEGGE DI CADORE, 01/06/2024

DI ESSE S.r.l.

EUDAMED: IT-MF-000036624

ADMINISTRATOR: Antonio De Silvestro.

DIESE
DI ESSE S.R.L. Via Vittorio Veneto 1, Fraz. Vallesella
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Di Esse S.r.l.
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www.diesse.com - E mail: diesse@diesse.com - Partita IVA e Codice Fiscale 001 3326 025 7



EU DECLARATION OF CONFORMITY

DI ESSE S.r.l., with registered office in Domegge di Cadore (BL), via Vittorio Veneto 1, location Domegge di Cadore, Italy, as manufacturer and under our sole responsibility hereby

declares

that the spectacle frames, in all its versions (colors and sizes)

CODE	DESCRIPTION	BASIC UDI-DI
PC1080V005500190	SMS327 55-16-140 190 PLS.FRAMES+SUN.CLIP	805759259 ACE NU
PC1080V005500800	SMS327 55-16-140 800 PLS.FRAMES+SUN.CLIP	805759259 ACE NU

are medical device complies with the provisions of Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) when combined with a magnetic clip-on.

The device complies with the following harmonized standards:

- EN ISO 12870:2018
- EN ISO 12312-1:2022

Conformity has been assessed according to the applicable procedures set forth in the aforementioned regulations.

DOMEGGE DI CADORE, 01/06/2025

DI ESSE S.r.l.

EUDAMED: IT-MF-000036624

ADMINISTRATOR: Antonio De Silvestro.



Di Esse S.r.l.
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EU DECLARATION OF CONFORMITY

We DI ESSE S.r.l., with registered office in Domegge di Cadore (BL), via Vittorio Veneto 1, location Domegge di Cadore, Italy, as manufacturer and under our sole responsibility herewith declare that the complies with:

SF1008S005400001	SMS346 54-20-140 1 PLS.SUNGLASSES
SF1008S005400005	SMS346 54-20-140 5 PLS.SUNGLASSES

- the (EU) Regulation 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment (PPE);
- the harmonized standard EN ISO 12312-1:2013/A1:2015 or to the EN ISO 12312-1:2022 standard on base of what is stated on the informative note that accompanies the product.

Place and date of issue:

DOMEGGE DI CADORE, 01/06/2025

Signed for and on behalf of DI ESSE S.r.l.

Antonio De Silvestro.

ADMINISTRATOR

DIESE
DI ESSE S.R.L. Via Vittorio Veneto 1, Fraz. Vallesella
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