FABÒOR

EU DECLARATION OF CONFORMITY

Manfroi Activity Srl, with registered office in via dell'Artigiano 11/E Mel -32026 Borgo Valbelluna (BL) Italy, C.F e P.IVA 01146560253 as manufacturer of spectacle frames under the brand "Fabòor"

declares under its sole responsibility

that the spectacle frame model

ALAN

in all its color variants:

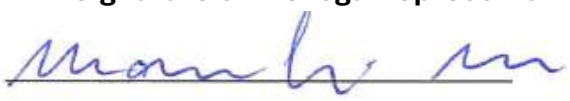
- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 14/11/2022

Signature of the legal representative



(Moreno Manfroi)

FABÒOR

EU DECLARATION OF CONFORMITY

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declares under its sole responsibility

that the spectacle frame model

ANDREA

in all its color variants:

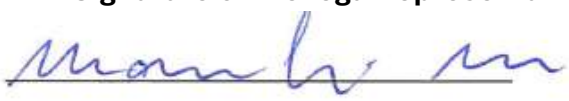
- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 14/11/2022

Signature of the legal representative



(Moreno Manfroi)

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declares under its sole responsibility

that the spectacle frame model

ANNA

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

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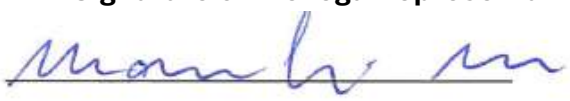
Borgo Valbelluna, 14/11/2022

Signature of the legal representative



(Moreno Manfroi)

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declares under its sole responsibility

that the spectacle frame model

ARIANNA

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

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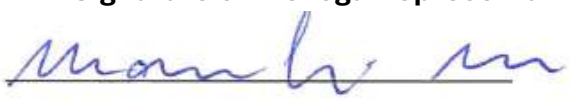
Borgo Valbelluna, 14/11/2022

Signature of the legal representative



(Moreno Manfroi)

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declares under its sole responsibility

that the spectacle frame model

BEATRICE

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 14/11/2022

Signature of the legal representative

(Moreno Manfroi)

Via dell'Artigiano 11/E Mel - 32026 Borgo Valbelluna (BL)
P.I. / C.F. 01146560253

EU DECLARATION OF CONFORMITY

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declares under its sole responsibility

that the spectacle frame model

BLOCK-01

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 20/01/2025

Signature of the legal representative

(Moreno Manfroi)

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declares under its sole responsibility

that the spectacle frame model

BLOCK-02

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

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Borgo Valbelluna, 20/01/2025

Signature of the legal representative

(Moreno Manfroi)

Via dell'Artigiano 11/E Mel - 32026 Borgo Valbelluna (BL)
P.I. / C.F. 01146560253

FABÒOR

EU DECLARATION OF CONFORMITY

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declares under its sole responsibility

that the spectacle frame model

BLOCK-03

in all its color variants:

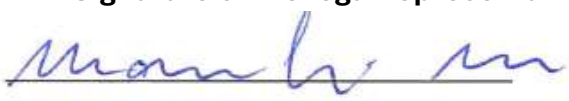
- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 20/01/2025

Signature of the legal representative



(Moreno Manfroi)

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EU DECLARATION OF CONFORMITY

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declares under its sole responsibility

that the spectacle frame model

CIMA

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

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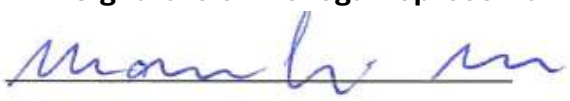
Borgo Valbelluna, 14/11/2022

Signature of the legal representative



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declares under its sole responsibility

that the spectacle frame model

CREST-01

in all its color variants:

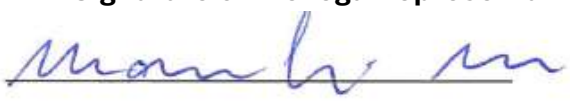
- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 01/09/2025

Signature of the legal representative



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EU DECLARATION OF CONFORMITY

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declares under its sole responsibility

that the spectacle frame model

CREST-02

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 01/09/2025

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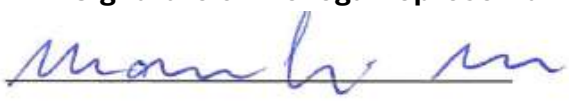

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declares under its sole responsibility

that the spectacle frame model

CREST-03

in all its color variants:

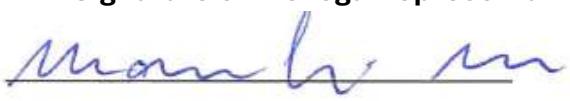
- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 01/09/2025

Signature of the legal representative



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declares under its sole responsibility

that the spectacle frame model

DANIEL

in all its color variants:

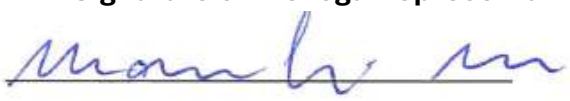
- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 03/08/2023

Signature of the legal representative



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EU DECLARATION OF CONFORMITY

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declares under its sole responsibility

that the spectacle frame model

DANTE

in all its color variants:

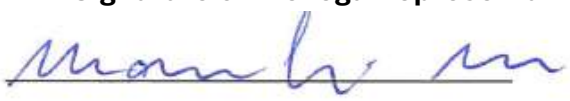
- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 14/11/2022

Signature of the legal representative



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that the spectacle frame model

DECO-01

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
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- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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Borgo Valbelluna, 20/01/2025

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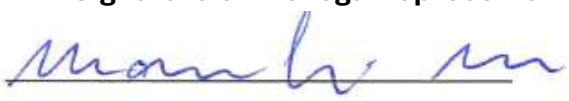

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declares under its sole responsibility

that the spectacle frame model

DECO-02

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
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- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

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Borgo Valbelluna, 20/01/2025

Signature of the legal representative

(Moreno Manfroi)

FABÒOR

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declares under its sole responsibility

that the spectacle frame model

DECO-03

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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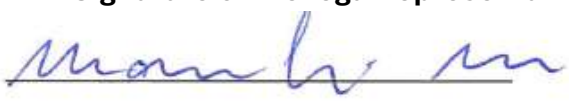
Borgo Valbelluna, 20/01/2025

Signature of the legal representative



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declares under its sole responsibility

that the spectacle frame model

DONDI

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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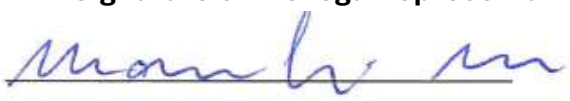
Borgo Valbelluna, 14/11/2022

Signature of the legal representative



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that the spectacle frame model

EDGE-01

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 20/01/2025

Signature of the legal representative

(Moreno Manfroi)

Via dell'Artigiano 11/E Mel - 32026 Borgo Valbelluna (BL)
P.I. / C.F. 01146560253

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declares under its sole responsibility

that the spectacle frame model

EDGE-01-M1

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 20/01/2025

Signature of the legal representative

(Moreno Manfroi)

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P.I. / C.F. 01146560253

FABÒOR

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declares under its sole responsibility

that the spectacle frame model

EMMA

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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Borgo Valbelluna, 14/11/2022

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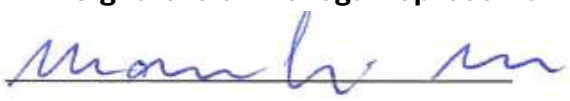

(Moreno Manfroi)

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declares under its sole responsibility

that the spectacle frame model

FIORE

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

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Borgo Valbelluna, 03/08/2023

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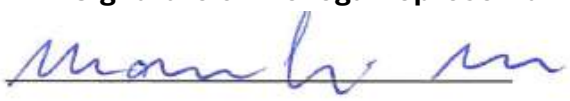

(Moreno Manfroi)

EU DECLARATION OF CONFORMITY

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declares under its sole responsibility

that the spectacle frame model

GALILEO

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

Basic UDI-DI**:** 805830168ALLU01A3

Eudamed Unique Manufacturer Registration Number: IT-MF-000040807

Borgo Valbelluna, 03/08/2023

Signature of the legal representative

(Moreno Manfroi)

Via dell'Artigiano 11/E Mel - 32026 Borgo Valbelluna (BL)
P.I. / C.F. 01146560253

FABÒOR

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declares under its sole responsibility

that the spectacle frame model

GIOVANNI

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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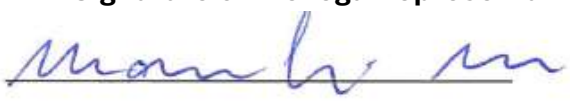
Borgo Valbelluna, 14/11/2022

Signature of the legal representative



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ITALO

in all its color variants:

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- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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Borgo Valbelluna, 14/11/2022

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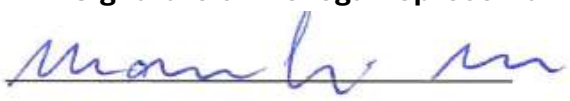

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declares under its sole responsibility

that the spectacle frame model

LAURA

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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Borgo Valbelluna, 14/11/2022

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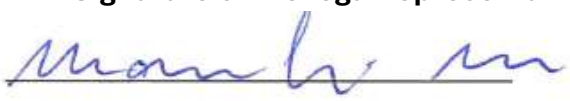

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declares under its sole responsibility

that the spectacle frame model

LEONARDO

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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Borgo Valbelluna, 03/08/2023

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declares under its sole responsibility

that the spectacle frame model

MARCO ANTONIO

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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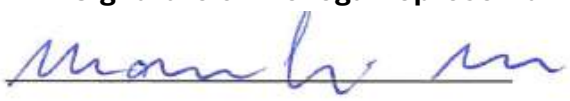

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MARYAM

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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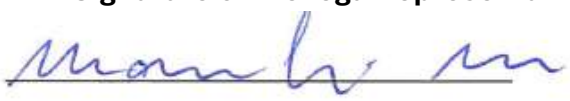

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that the spectacle frame model

MAURUS

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
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- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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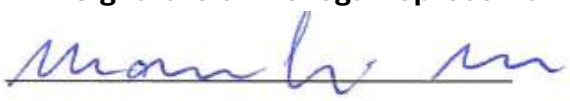

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that the spectacle frame model

MICHELANGELO

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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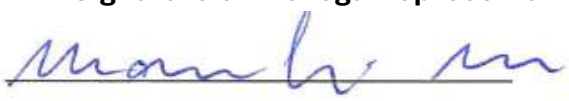

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that the spectacle frame model

MORENO

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
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- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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that the spectacle frame model

PALLADIUM

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
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- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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that the spectacle frame model

PIETRO

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
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- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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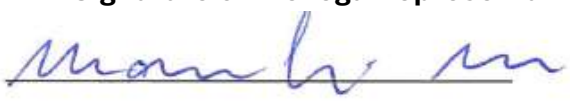

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that the spectacle frame model

SOFIA

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
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- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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that the spectacle frame model

WAVE-01

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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Borgo Valbelluna, 20/01/2025

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that the spectacle frame model

WAVE-02

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
- complies with the provisions of EU Regulation 2017/745 applicable to Class I medical devices;
- complies with ISO 12870.
- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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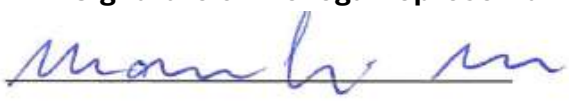

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WAVE-03

in all its color variants:

- is a Class I medical device within the meaning of Article 4, Part II, of Annex VIII to Regulation (EU) 2017/745;
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- complies with ISO 16128 (metal frames and/or metal parts in direct and prolonged contact with the skin)

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