Innova Vision Inc.
No.18, Prosperity Rd. 1, Hsinchu Science
Park 300091, HsinChu, Taiwan R.O.C.
TEL: +886-3-5927299

EC Declaration of Conformity

Exclusively responsible for Innova Vision Inc.
No.18, Prosperity Rd. 1, Hsinchu Science Park 300091, HsinChu, Taiwan R.O.C.

(1) hereby declares the following devices:

- Product Name: I-Lux Innova Soft Contact Lens
- Type: Single use
- Product Code: EB-S
- Models: Daily Disposable Soft Contact Lens with UV blocker
- Models Code: A91
- Class: IIa

Brands:

- Eyewear 10 daily soft contact lenses*

*: Detail information of product, please find appendix for reference.

(2) Declaration in conformity with the essential requirements of the following directives:
Medical Devices Directive 93/42/EEC

(3) The manufacturer and its Personnel shall comply with all applicable Rules and shall ensure that the Products are compliant with applicable Rules. and be exclusively responsible as stated in Section 3 of MDD assessment reports.

(4) Meet the requirements of Annex II (excluding Section 4) to be certified by **DNV (Notify Body Number:2460)**, Address: Veritasveien 1, N-1363 Høvik, Norway. For the evaluation regarding the Group 5, Class IIa product safety aspects.

(5) The following European Authorized Representative is stated to the declaration:
Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

(6) This declaration of conformity is issued under the sole responsibility of the manufacturer.

(7) References to the relevant harmonized standards used, or references to the specifications in relation to which conformity is declared:

Harmonized standards:

- EN ISO 13485:2016, Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
- EN ISO 10993-1:2020, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)
- EN ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
- EN ISO 10993-11:2018, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)

- EN ISO 10993-12:2021, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
- EN ISO 10993-13:2010, Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)
- EN ISO 10993-16:2017, Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2017)
- EN ISO 10993-17:2009, Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)
- EN ISO 10993-18:2020, Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2020)
- EN ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)
- EN ISO 11737-1:2018, Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
- EN ISO 11737-2:2020, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
- EN ISO 15223-1:2021, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2021)
- EN 1041:2008, Information supplied by the manufacturer of medical devices
- EN ISO 11607-1:2020, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
- EN ISO 11607-2:2020, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
- EN ISO 14971:2019, Medical devices - Application of risk management to medical devices (ISO 14971:2019)
- EN 62366-1:2015, Medical devices –Part 1: Application of usability engineering to medical devices
- IEC 62366-1:2015, Medical devices –Part 1: Application of usability engineering to medical devices

Non Harmonizes Standards:

- ISO 18369-1:2017, Ophthalmic optics -- Contact lenses -- Part 1: Vocabulary, classification system and recommendations for labelling specifications
- ISO 18369-2:2017, Ophthalmic optics -- Contact lenses -- Part 2: Tolerances
- ISO 18369-3:2017, Ophthalmic optics -- Contact lenses -- Part 3: Measurement methods
- ISO 18369-4:2017, Ophthalmic optics -- Contact lenses -- Part 4: Physicochemical properties of contact lens materials
- ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing

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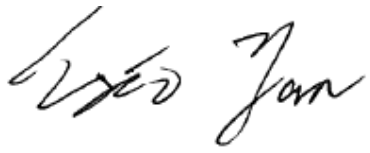
within a risk management process

- ISO 10993-10:2021, Biological evaluation of medical devices -- Part 10: Tests for skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices -- Part 23: Tests for irritation
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems(ISO 11607-2:2019)
- ISO 11737-1:2018, Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
- ISO 11737-2:2019, Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 11981:2017, Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of physical compatibility of contact lens care products with contact lenses
- ISO 11978:2017, Ophthalmic optics -- Contact lenses and contact lens care products – Labelling
- ISO 11987:2012, Ophthalmic optics -- Contact lenses -- Determination of shelf-life
- ISO 14534:2011, Ophthalmic optics -- Contact lenses and contact lens care products -- Fundamental requirements
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- FDA Guidance for Industry on Sterile Drug Products Produced by Aseptic Processing （September, 2004）
- IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices

Signed by Innova Vision Inc.'s designated representative:



Eric Yan
Management Representative
Date: 14 Mar., 2025

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- **Appendix**

PO.No	Power	Customer article no	Description	GTIN-13 (EAN-13)
BO-250433	-1.00	2536378	Eyewear 10 daily soft contact lenses -1.00	4719889751793
	-1.50	2536378	Eyewear 10 daily soft contact lenses -1.50	4719889751809
	-2.00	2536378	Eyewear 10 daily soft contact lenses -2.00	4719889751816
	-2.50	2536378	Eyewear 10 daily soft contact lenses -2.50	4719889751823
	-3.00	2536378	Eyewear 10 daily soft contact lenses -3.00	4719889766834