

## EU Declaration of Conformity

**Manufacturer name and address:** ExamVision A/S,  
Industrivej 11, Tranebjerg, 8305 Samsø, Denmark

**Actor ID/SRN:** DK-MF-000032397

**To whom it may concern,**

We,

**ExamVision A/S, Industrivej 11, Tranebjerg, 8305 Samsø, Denmark**

hereby declare under our sole responsibility that the devices listed in the attached Annex comply with the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

This Declaration is applicable to the devices listed in the Annex to the Declaration of Conformity. Basic UDI-DI, risk class and classification rules according to Annex VIII of REGULATION (EU) 2017/745 and intended purpose are provided in the Annex to the Declaration of Conformity.

The following conformity assessment procedure has been performed following Article 19 and Article 52 (7) of the Regulation (EU) 2017/745 and Technical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.

The following Standards have been used and in relation to which conformity is declared:

- ISO 14971:2019
- IEC 62366-1:2015

**Issue place and date:** Samsø, 29 July 2025

**Signature:**




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**Ole Anker Aagaard/Head of Legal**

## Annex – List of devices covered by the Declaration of Conformity

### Device Category: Eyewear

**Intended purpose statement:** The ExamVision Eyewear is a non-sterile, non-invasive optical device intended to be used as a visual **compensation** aid by any individual aged 16 years or older with refractive vision impairment, who has a valid optical prescription issued by a qualified healthcare professional (e.g., optometrist or ophthalmologist). The device is suitable for daily use in personal, professional, and health care settings.

The ExamVision Eyewear has compatibility to be used with ExamVision Loupe System and Light System. In that scenario, it will follow the intended use statement of 'Loupe System and Light System' as applicable.

#	Trade name	Device Category	Classification	Catalogue No	BASIC UDI - DI	GTIN (UDI - DI)
1	Carbon v1	Eyewear	Class I, Rule I	Carbonv1	574400023EVEyewearDV	05744000230122
2	Carbon v2	Eyewear	Class I, Rule I	Carbonv2	574400023EVEyewearDV	05744000230115
3	Curve	Eyewear	Class I, Rule I	Curve	574400023EVEyewearDV	05744000230108
4	Icon v2	Eyewear	Class I, Rule I	Iconv2	574400023EVEyewearDV	05744000230269
5	Metro	Eyewear	Class I, Rule I	Metro	574400023EVEyewearDV	05744000230245
6	Panto	Eyewear	Class I, Rule I	Panto	574400023EVEyewearDV	05744000230092
7	Sport v2	Eyewear	Class I, Rule I	Sportv2	574400023EVEyewearDV	05744000230238