

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, 09 Feb 2026

Signature:



Ole Anker Aagaard/Head of Legal

Annex – List of devices covered by the Declaration of Conformity

Device Category: Loupe System

Intended purpose: The ExamVision Loupe System is a non-sterile, non-invasive optical medical device intended to be used by trained healthcare professionals to magnify the visual field during the performance of medical or dental procedures. The system is designed for use in professional healthcare environments and does not come into direct contact with patients or sterile fields during use. It is not intended for diagnostic or therapeutic purposes.

#	Trade name	Intended Purpose	Classification (EU MDR)	Catalogue No	BASIC UDI - DI	GTIN (UDI - DI)
1	Essential 2.5x	The Loupe System	Class I, Rule I	ESS25	574400023EVLoupeXD	05744000230030
2	Essential 3.0x	The Loupe System	Class I, Rule I	ESS30	574400023EVLoupeXD	05744000230283
3	Galilean Essential 2.5x	The Loupe System	Class I, Rule I	ESSBIO25	574400023EVLoupeXD	05744000230047
4	Galilean Essential 3.0x	The Loupe System	Class I, Rule I	ESSBIO30	574400023EVLoupeXD	05744000230276
5	Galilean HD 2.3x	The Loupe System	Class I, Rule I	HD23	574400023EVLoupeXD	05744000230054
6	Galilean HD 2.8x	The Loupe System	Class I, Rule I	HD28	574400023EVLoupeXD	05744000230290
7	Galilean HD 3.3x	The Loupe System	Class I, Rule I	HD33	574400023EVLoupeXD	05744000230306
8	Galilean HD 3.8x	The Loupe System	Class I, Rule I	HD38	574400023EVLoupeXD	05744000230313
9	Kepler Kompakt 3.5x	The Loupe System	Class I, Rule I	KK35	574400023EVLoupeXD	05744000230061
10	Kepler Kompakt 4.6x	The Loupe System	Class I, Rule I	KK46	574400023EVLoupeXD	05744000230320
11	Kepler Kompakt 5.7x	The Loupe System	Class I, Rule I	KK57	574400023EVLoupeXD	05744000230337
12	Kepler Kompakt 3.4x	The Loupe System	Class I, Rule I	KK34	574400023EVLoupeXD	05744000230061
13	Kepler Kompakt 5.0x	The Loupe System	Class I, Rule I	KK50	574400023EVLoupeXD	05744000230320
14	Kepler Kompakt 7.6x	The Loupe System	Class I, Rule I	KK76	574400023EVLoupeXD	05744000230337
15	Kepler Advanced v2	The Loupe System	Class I, Rule I	KA70	574400023EVLoupeXD	05744000230252
16	Kepler Reflekt 4.0x	The Loupe System	Class I, Rule I	KR40	574400023EVLoupeXD	05744000230085
17	Kepler Reflekt 6.0x	The Loupe System	Class I, Rule I	KR60	574400023EVLoupeXD	05744000230344