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,
- DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and
- REGULATION (EC) 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.

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:

- IEC 60601-1:2005 + A1:2012 + A2:2020
- IEC 60601-1-2:2014 + A1:2020
- IEC 60601-1-6 + A1:2+13 + A2:2020
- IEC 62471:2006
- ISO 14971:2019
- IEC 62366-1:2015

Issue place and date: Samsø, 29 July 2025

Signature:

_____

Ole Anker Aagaard/Head of Legal

Annex – List of devices covered by the Declaration of Conformity

Device category: Light system

Intended Purpose: The ExamVision Light System is a non-sterile, battery-powered, active medical device intended to aid healthcare professionals by providing focused illumination to the visual field during medical or dental procedures. The system is designed for use in controlled professional healthcare environments and must not come into direct contact with patients or sterile fields during use. It is not intended for diagnostic or therapeutic purposes.

#	Trade name	Device Category	Classification (EU MDR)	Catalogue No	BASIC UDI - DI	GTIN (UDI - DI)
1	Total Intense (6500 K) LED	Light System	Class I, Rule 10	20790	574400023EVLightsHU	05744000230023
2	Total Pure (5000 K) LED	Light System	Class I, Rule 10	20789	574400023EVLightsHU	05744000230016
3	Power Go	Light System	Class I, Rule 10	20791	574400023EVLightsHU	05744000230009