

## EC Declaration of Conformity

To whom it may concern,

Samsø, Denmark, May 2024

We,

**Exam Vision ApS, Industrivej 11, Tranebjerg, 8305 Samsø, Denmark**

hereby declare in our capacity as the product manufacturer, that the Light System Essential Alpha which is intended to be used

*as a visual aid, illuminating the visual field for the Healthcare Professional while performing medical procedures,*

complies with the requirements of the

*REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC with amendments.*

<b>Actor ID/SRN:</b>	DK-MF-000032397
<b>Basic UDI-DI:</b>	574400023EVLight5F
<b>Product Name/Trade name:</b>	Essential Alpha
<b>Intended Purpose:</b>	The Light System is intended to be used as a visual aid, illuminating the visual field for the Healthcare Professional while performing medical procedures.
<b>Risk Class (MDR):</b>	Class I, rule I.
<b>Conformity Assessment Route:</b>	Annex I General Safety and Performance Requirements Annex II Technical Documentation Annex III Technical Documentation on Post-Market Surveillance
<b>Other relevant legislation, applicable harmonised standards, and normative documents:</b>	RoHS & REACH 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

Issue date: 1 May 2024



Signature:



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**Ole Anker Aagaard/Head of Legal**