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 Focus Bright 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.

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

CE

Signature:

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Ole Anker Aagaard/Head of Legal