EXAMVISION™ Magnification Ergonomics

EC Declaration of Conformity Certificate

To whom it may concern

Samsø, Denmark, May 2021

We,
ExamVision ApS, Industrivej 11, Tranebjerg, 8305 Samsø, Denmark
Hereby declare on our own responsibility as the manufacturer, that the four variants (see the table below) of the Medical Device: ExamVision Loupe System / Magnifying loupes with the following intended use:

The loupe system is used as an assistive technology by the dentist and surgeon when studying/diagnosing/operating and working on the patient.

Meet all of 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 (MDR).

Issue	**Comments**
Product names of the four variants of the ExamVision Loupe System	• Essential Loupe • Kepler Kompakt Loupe • Galilean HD Loupe • Kepler Advanced Loupe
Product description	Magnifying loupes
Eudamed reference	DVC-DK-15-04-000631 DVC-DK-15-04-000632 DVC-DK-15-04-000633 DVC-DK-20-01-000073
Serial number EV: ExamVision XXXXXXX: Unique number	EVXXXXXXX
GS1 barcode/Basic UDI	574400023
Classification according to MDR	Class I, rule 1.
Single registration number	N/A
Route of conformity for all variants of the product	Annex I General safety and performance requirements. Annex II Technical documentation. Annex III Technical documentation on post-market surveillance.
Other relevant legislation, applicable harmonized standards, and normative documents.	RoHS ISO 12870:2018 ISO 21987:2017 ISO 14971:2019 See *List of legislation, standards and guidelines.*
Manufacturer: **Telephone:** **Owner/ Position:** **Company No.:**	ExamVision ApS +45 87 92 12 10 Kim Jensen/ CEO CVR 26174430
Date: 14.05.21	**Signature:** Kim Jensen/ CEO