The products presented by this declaration are in conformity with the listed regulations. The manufacturer is exclusively responsible for this declaration of conformity.

Manufacturer	
Name, registered trade name or registered trademark	CMS Dental A/S
Address	Elmevej 8, 7870 Roslev, Denmark
Single registration number (SRN)	DK-MF-000020260

Product Information	
Product description	Photosensitizer Light
Product and accessories trade names	See appendix List of products
Intended purpose	The Light is used as a photosensitizer light for light activated disinfection (LAD) to eliminate bacterial growth in the biofilm of the root canals and of soft and hard tissue. The photosensitizer light must be used in conjunction with a photosensitizer agent.
Basis UDI-DI	5713223PHL1YS

Region	**Classification (Risk Class & Rule)**	**Regulation Conformity**
EU	Medical Device: Class I, rule 5	European Medical Device Regulation 2017/745
USA	Medical Device: Class I	Code of Federal Regulations, CFR 21 800-898 Medical Devices

Standard compliance	
ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN 60601-1:2006 /A1:2013 /A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 2768-1:2002	General tolerances – Part 1: Tolerances for linear and angular dimensions without individual tolerance indications
ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

Competent Authority	
Name Address Phone	Danish Medicines Agency, Pharmacovigilance & Medical Devices Axel Heides Gade 1, 2300 Copenhagen S, Denmark +45 4488 9595
EUDAMED Actor ID	DK-CA-042
Conformity assessment procedure	Medical Device Regulation 2017/745 Annex II (TD) | Annex III (PMS) | Annex IX, Chapter I (QMS) | Article 19/Annex IV (DoC) Quality Management System – Medical devices ISO 13485:2016 & EN ISO 13485:2016
Identification of certificate(s)	Quality Management System – Medical devices

Certificate	Certificate no.	Issuer (NB ID)	Issued	Valid until
ISO 13485:2016 & EN ISO 13485:2016	MD 810095	BSI (2797)	2025-01-22	2028-01-22

CMS Dental, the manufacturer, hereby declares that the listed products manufactured after the release date of this declaration of conformity are covered by this declaration of conformity and comply with the above-mentioned regulations, relevant product standards and their transposition into national laws of the member states into which we place the device.

Approval, on behalf of CMS Dental A/S		
Name / Title / Signature	Lisbeth Rose / Quality Assurance Director	
Place / Date of issue	Copenhagen / 2025-01-27	

Appendix – List of products

Products

Product and trade name	Item no.	GTIN/UDI	EUDAMED DI (Basis UDI-DI)
FotoSan 630 LAD Light	100411	5713223000225	5713223PHL1YS

Accessories

Product and trade name	Risk Class/Rule	Item no.	GTIN/UDI
Tips BLUNT d4mm	Class I / rule 5	100501	5713223000652
Tips BLUNT d8mm	Class I / rule 5	100502	5713223000669
Tips PERIO L23mm	Class I / rule 5	100503	5713223000676
Tips PERIO L15mm	Class I / rule 5	100504	5713223000683
Tips ENDO	Class I / rule 5	100505	5713223000690
Covers	Class I / rule 5	100510	5713223000881
Dental Sleeve Open - 250pcs	Class I / rule 5	100512	5713223000379
Dental Sleeve Closed - 250pcs	Class I / rule 5	100513	5713223000386
Protection Shield	Class I / rule 5	100500	5713223001376
Protection Shield Click-on	Class I / rule 5	100511	5713223001383