

Declaration of Conformity

This Declaration of Conformity covers the European Medical Device Regulation 2017/745. The information included in this declaration fulfills the requirements in Annex IV, EU Declaration of Conformity.

The devices covered by the present declaration is in conformity with this regulation.


Manufacturer	
Name, registered trade name or registered trademark	CMS Dental A/S
Single registration number, SRN	Currently not available from Danish Health and Medicines Authority
Danish Health and Medicines Authority, NCA code	DK-CA-001
Eudamed reference	DK-CA-001
Address	Elmevej 8 7870 Roslev Denmark

Product Information	
Product description	Curing and Photosensitizer Lights
Intended purpose	Their intended purpose is curing of dental composite and elimination of bacteria's embedded in the dental biofilm of root canals and on mucous tissue. <ul style="list-style-type: none"> The curing lights are used in Dentistry for polymerization of Dental composite materials. The photosensitizer lights are used in conjunction with a photosensitizer agent to eliminate bacterial growth in the biofilm.
Risk class	Class I
References to CS used	There are no Common Specification available for this type of products in the Official Journal of the European Union.

Product and trade name	Item no.	Customer Item no.	UDI	Eudamed reference
FlashMax P3 Cure and Ortho	100400	na	571322300010	DVC-DK-18-10-000596
FlashMax P3 Cure and Ortho Wide Spectrum	100403	na	571322300020	DVC-DK-18-10-000596
FlashMax P7 LAD	100420	na	571322300009	To be defined
FotoSan 630 LAD	100411	na	571322300022	DVC-DK-18-10-000594
Dentalica				
LuminaMax	PR00LMAX	PR00LMAX	571322300011	DVC-DK-18-10-000596
LuminaMax LAD	PR00LMAXL	PR00LMAXL	571322300012	To be defined
RMO				
FlashMax P4 Ortho Pro	100406	OJO2130	571322300021	DVC-DK-18-10-000597

Notified Body	
Name	DNV GL Presafe AS
Notified Body identification number	2460
Conformity assessment procedure	<u>Quality Management System – Medical devices</u> ISO 13485:2016/NS-EN ISO 13485: 2016 <u>Medical Device Regulation 2017/745</u> Annex II (TD) Annex III (PMS) Annex IX, Chapter I (QMS) (Annex IX, Chapter III) [only a requirement outside of EU] Article 19/Annex IV (DoC)
Identification of certificate(s)	<u>Quality Management System – Medical devices</u> ISO 13485:2016/NS-EN ISO 13485: 2016 Certificate number: 268826-2018-AQ-NOR-NA-PS Rev. 0.0 Issue date: 11 December 2018 Valid until: 10 December 2021 Issued by: DNV GL Presafe AS

We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Regulation 2017/745 and its relevant transposition into national laws of the member states into which we place the device. The manufacturer is exclusively responsible for the declaration of conformity.

Approval	
On behalf of CMS Dental A/S	
Signature	
Name / Function	Lisbeth Rose / Quality Manager
Place	Copenhagen
Date of issue	2021-03-19