



DECLARATION OF CONFORMITY

VALO GRAND

Ultradent Products Inc., 505 West Ultradent Drive (10200 South), South Jordan, UT, 84095, has evaluated this product by using the Conformity Assessment Procedure of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and confirms that this product is compliant with the General Safety and Performance Requirements of Annex I of the Regulation (EU) 2017/745. Technical documentation is located in the Regulatory Affairs Department.

EC Representative:	Ultradent Products GmbH Am Westhover Berg 30 51149 Cologne Germany
Device Classification:	This product system is classified as a Class I medical device according to Regulation (EU) 2017/745, Annex VIII, Chapter III, Section 6.5, Rule 13.
Intended Purpose:	Source of illumination for curing photo-activated dental restorative materials and adhesives.
UMDNS Code:	16386 – Light, Dental Activator
GMDN Code:	35775 – Light, Dental, polymerization activator
CND Code:	Z12119003 – Cold Light Dental Equipment
Basic UDI-DI:	0883205-TF086BF
Eudamed SRN:	DE-AR-000006666, DE-IM-000010855, US-MF-000013697
Model Numbers:	5972-, 4866-, 4864-, 4865-
Images:	

This Declaration of Conformity is issued under the sole responsibility of the manufacturer and is in force as long as the following certificates are valid:

ISO 13485:2016 Certificate 19-1612-Q valid through 15 Feb 2026
acc. to ISO 13485:2016 Certificate 19-1613-M valid through 15 Feb 2026



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Adam Black
Adam Black
Regulatory Affairs Manager

29 March 2023
Date

State of Utah, County of Salt Lake
Subscribed and sworn to before me on this

29 day of March 2023
By Adam Black

Amy Henderson-Nielson
Notary Public

