

# DECLARATION OF CONFORMITY

## VALO, VALO GRAND CORDED



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.

<b>EC Representative:</b>	Ultradent Products GmbH Am Westhover Berg 30 51149 Cologne Germany
<b>Device Classification:</b>	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.
<b>Intended Purpose:</b>	Source of illumination for curing photo-activated dental restorative materials and adhesives.
<b>UMDNS Code:</b>	16386 – Light, Dental Activator
<b>GMDN Code:</b>	35775 – Light, Dental, polymerization activator
<b>EMDN Code:</b>	Z12119003 – Cold Light Dental Equipment
<b>Basic UDI-DI:</b>	0883205-TF112AP
<b>Eudamed SRN:</b>	US-MF-000013697
<b>Model Numbers:</b>	5919-, 5971-
<b>Images:</b>	The image shows two dental curing light units, one labeled 'VALO' and one labeled 'VALO GRAND'. Each unit consists of a black rectangular box with a blue light source, a black handle, and a black cord. The units are shown with their respective accessories, including a black carrying case and a black power adapter.

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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

*Adam Black*  
Adam Black, RAC  
Manager – Regulatory Affairs

30 March 2023  
Date

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

30 day of March 20 23  
By Adam Black

*Amy Henderson-Nielson*  
Notary Public

