

# DECLARATION OF CONFORMITY

## VALO AND VALO GRAND ACCESSORIES

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 5.1, Rule 5.
<b>Intended Purpose:</b>	The VALO Accessory Lenses are multiple-use accessory lenses intended to provide illumination to aid in visualization during oral procedures and augment the VALO family of curing lights, which are a source of illumination for curing photo-activated dental restorative materials and adhesives. VALO Accessory Lenses are not intended for complete cure of photo-activated materials and adhesives.  VALO Light Shields are intended to be used in conjunction with the VALO curing light as a protective measure during use.
<b>UMDNS Code:</b>	16386 – Light, Dental Activator
<b>GMDN Code:</b>	35775 – Light, Dental, polymerization activator
<b>CND Code:</b>	Z12119003 – Cold Light Dental Equipment
<b>Basic UDI-DI:</b>	0883205-TF086BF
<b>Eudamed SRN:</b>	DE-AR-000006666, DE-IM-000010855, US-MF-000013697
<b>Model Numbers:</b>	5934-, 5936-, 5937-, 5939-, 4629-, 4082-, 4081-, 4084-, 4319-, 4628-, 4658-, 3604-, 5929-, 5935-

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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

  
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Adam Black  
Senior Manager – Regulatory Affairs

07 September 2023  
Date

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

7 day of September 2023  
By Adam Black

  
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Notary Public

