DECLARATION OF CONFORMITY



VALO AND VALO GRAND ACCESSORIES

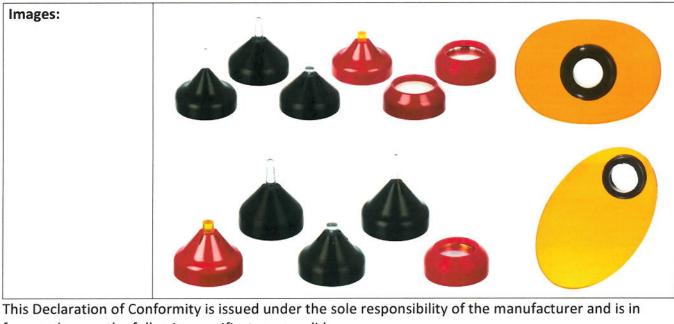
Ultradent Products Inc., 505 West Ultradent Drive (10200 South), South Jordan, UT, 84095, has evaluated this product by using the Conformity Assessment Procedure of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and confirms 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.

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 5.1, Rule 5.			
Intended Purpose:	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.			
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:	5934-, 5936-, 5937-, 5939-, 4629-, 4082-, 4081-, 4084-, 4319-, 4628-, 4658-,			
	3604-, 5929-, 5935-			

DECLARATION OF CONFORMITY



VALO AND VALO GRAND ACCESSORIES



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	**	16 	07 Septe	mber
Senior Manager – Regulat	ory Affairs			
State of Utah, County of Salt Subscribed and sworn to befo				
day of Sep	tember	20 23		
By Adam Black				
Array Henderson. (Julan		Amy Her	nderson-N

NOTARY PUBLIC - STATE OF UTAH My Comm. Exp. 08/03/2024 Commission # 713340

Notary Public

2023