

DECLARATION OF CONFORMITY

VALO X AND VALO X ACCESSORY LENSES



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

A handwritten signature in blue ink, appearing to read 'Adam Black', written over a horizontal line.

Adam Black

Senior Manager – Regulatory Affairs

28 May 2024
Date

State of Utah, County of Salt Lake

Subscribed and sworn to before me on this

28 day of May 2024

By Adam Black

A handwritten signature in blue ink, appearing to read 'Amy Henderson-Nielson', written over a horizontal line.

Notary Public



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VALO X AND VALO X ACCESSORY LENSES



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:	VALO X is classified as a Class I medical device according to Regulation (EU) 2017/745, Annex VIII, Chapter III, Section 6.5, Rule 13. VALO X Accessory Lenses 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:	VALO X curing light is a source of illumination for curing photo-activated dental restorative materials and adhesives. It is also intended to provide illumination to aid in visualization during oral procedures. VALO X curing light accessory/diffuser lenses are not intended for complete cure of photo-activated materials and adhesives.
UMDNS Code:	16386 – Light, Dental Activator
GMDN Code:	35775 – Light, Dental, polymerization activator
EMDN Code:	Z12119003 – Cold Light Dental Equipment
Basic UDI-DI:	0883205-TF370BF
Eudamed SRN:	DE-AR-000006666, DE-IM-000010855, US-MF-000013697
Model Numbers:	5973-, 5893-, 5892-, 5891-, 5889-, 5890-
Images:	