



Certificate of Accreditation

AccuLens
5353 W Colfax Ave
Denver, CO 80214

has successfully completed the requirements for accreditation as an alternate manufacturing site of Contamac and is operating in compliance with the Quality System Regulation as depicted in the FDA 21 CFR Part 820. The finishing laboratory has been evaluated in accordance with, and found to conform to, all provisions of the procedure for adding Lens Finishing Laboratories for Manufacturing and Marketing of Class II (RigidGas Permeable) RGP Contact Lenses.

Valley Contax is hereby accredited to manufacture finished GP lenses from the Contamac OPTIMUM GP and HEXA100 materials.



OPTIMUM GP (Oxygen Permeable)

Regulatory Approval:	K033594, K062548, K070628, K160859, K180616, K171077, K182304, K212631
USAN:	(rofluvocon A) (rofluvocon C) (rofluvocon D) (rofluvocon E) (hexafocon A) (tisilfocon A)
Regulation Name:	Rigid Gas Permeable, Contact Lenses for Daily Wear (clear and tinted)
Product Code:	HDQ
Regulation Number:	21 CFR 886.5916
Regulatory Class:	Class II
Indications/Designs:	Single Vision, Toric, Multifocal, Irregular Cornea, Scleral, Daily Wear Orthokeratology, and therapeutic use, all available with plasma treatment*

*Note: Not all materials are approved for all indications listed. Refer to 510K summaries for each material for complete indications for use. Use of Tangible® Hydra-PEG® requires a separate authorization.

Vice President of US Operations

This certificate is valid until December 31, 2024.