

PROTOCOL # 918-C

CONTACT CASE

Performance Test	Test Method	Samples	Requirement	Rating (Section or exec. Summary which failed items can be referenced)
LABELING				
Labeling/Packaging	F.P. & L. Act (16 CFR 500)	1 Sample	Should be legibly marked with the following information: Distributor's name, trademark or other means of identification of the manufacturer or packer & address (City, State & Zip) Product identification Net quantity of the contents in terms of weight, measure or numerical count (Metric & US Standard) or a combination so as to give accurate information and facilitate value comparison by the consumer Country of origin (if imported)	
**Country of Origin Marking	19 CFR 134	1 Sample	Shall indicate country of origin legibly, permanently, and in comparable size and close proximity to any mention of country other than country in which the article was manufactured or produced. Must be visible at point of purchase.	
Lens Case Warnings	21 CFR 886.5918 & 886.5928 Premarket Notification Document for Contact Lens Care Products, Appendix B – Lens Cases	1 Sample	For all lens cases: Lens cases can be a significant source of microbial contamination. To help prevent eye infections, lens cases should be cleaned, rinsed and air dried every day; and replaced frequently (as recommended by the manufacturer). For lens cases indicated for use in chemical disinfection only: Use of this lens case with heat may cause warpage. USE FOR STORAGE DURING CHEMICAL DISINFECTION ONLY. DO NOT USE WITH HEAT.	
Lens Case – Direction for Use	Premarket Notification Document for Contact Lens Care Products, Appendix B – Lens Cases	1 Sample	General Instructions: [Include preparing the lens case for use and how to care for the lens case daily.] Specific Instructions: [Include step-by-step instructions for use.]	
Lens Case Indications	Premarket Notification Document for Contact Lens Care Products, Appendix B – Lens Cases	1 Sample	Include additional limiting information (if applicable): For stage only – not for use as a container for heat or chemical disinfection. Use for stage during chemical disinfection only. DO NOT USE WITH HEAT.	
Lens Case Labeling	Premarket Notification Document for Contact Lens Care Products, Appendix B – Lens Cases	1 Sample	The following information is required: Include information that expresses the facts: [Distributed by / Manufactured by / Manufactured for] and address, including zip code Lot No. Printed [Month and Year]	
Premarket Notification 510(k) Clearance	Premarket Notification Document for Contact Lens Care Products	1 Sample	The vendor shall make a 510 (k) submission to the Center for Devices and Radiological Health (CDRH) and provide testing lab with a copy of the letter they received from CDRH permitting commercial clearance.	
Use Labeling	Visual Check	1 Sample	Use/care instructions that are clear and understandable shall be provided in English.	
Claim Verification (if claimed)	Visual Check/ Actual Use	All	All designs and features must conform to actual claim	
Adult Tracking Label: **If space limitations exist, contact Kohl's Quality Assurance & Product Integrity teams to discuss minimum required information mr.qa.pi@kohls.com	Kohl's Requirement	All	Can be included on packaging when necessary: Kohl's Assigned Factory Number Manufacture Date (Month/Year) UPC #	
PHYSICAL CHARACTERISTICS				
Dimensions	Std. Measurement	3 Samples	Report overall dimensions; shall meet label claims (if applicable).	Claim: Actual:
Weight	Std. Measurement	3 Samples	Report overall weight; shall meet label claims (if applicable).	Claim: Actual:
Capacity (Volumetric)	Std. Measurement	3 Samples	Report overall capacity; shall meet label claims (if applicable).	Claim: Actual:
Parts Inventory	Visual Check	1 Sample	Shall meet label claims.	
CONSTRUCTION & WORKMANSHIP				
Kohl's Workmanship Review	Visual Check/Actual Use	All	All components shall be provided as claimed and shall not be deformed or fractured. All hardware shall be provided All welds shall be smoothly finished and free from pits and splatter All components shall not contain any burrs or sharp edges (test by touch or sight) Product shall not contain any loose components or unsecured fastening where rigidity is required Filling material shall be free of objectionable matter and contaminants.	
PERFORMANCE				
Functionality (not already covered by other tests)	Actual Use	All	Shall function as intended as received. Report details of evaluation (features tested / methods used / materials used / etc.) Report any features not evaluated.	
Lid Open/Close Test	Actual Use	1 Sample	Disposable Cases: No failure when opening and closing the case 10 times Non-disposable Cases: No failure when opening and closing the case 100 times	
Leakage	Actual Use	1 Sample	Shall not leak water when placed on side for 10 minutes.	

Effects Of Handwashing	Kohl's TM 32	1 Sample	No color change and no adverse effects – Hand wash with detergent for no. of cycles Tier 1:5 Cycles Tier 2: 10 Cycles
Resistance to Corrosion	Kohl's TM 31	1 Sample	No major visual change, corrosion or staining after 24 hours @ 100° F (38° C) and 99% R.H.

ANALYTICAL

*Lead in Scrapable Surface Coating	ASTM E1613/E1645	1 Sample	≤90 ppm (0.009% by weight). (CPSA - 16 CFR 1303)
CA Prop 65	Refer to Protocol 1300	All Samples	All samples shall be reviewed against the requirements of California Proposition 65 to determine if additional testing or labeling is required

***Please refer to Kohl's preferred third party labs for individual pricing and sample size**
In addition to this protocol, any products designed for, intended for or appealing to children, requires additional testing per Testing Protocol # 601.

Protocol Version	Description of Change	Revised by / Date	Approved by / Date
918-A	Protocol Created	Zoe Yeung Mar. 17, 2015	Elizabeth Armstrong March 17, 2015
918-B	Added adult tracking label requirements	Elizabeth Armstrong June 15, 2020	Elizabeth Armstrong June 15, 2020
918-C	removed level 3 tiering from Effects Of Handwashing	Elizabeth Armstrong Dec 2021	Elizabeth Armstrong Dec 2021