State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Oculus Optikgerate Recalls Oculus Pentacam for Insufficient Anti-Reflective Coating

Recall Date	Product Description	Recalling Firm	Recall Reason
9/6/2023	**Oculus Pentacam Axl Wave** Ref 70020, CE 0123	**OCULUS OPTIKGERAETE GMBH** Wetzlar, Germany	There is a potential that optical devices with insufficient anti-reflective coating may lead to incorrect axial length measurements.
9/6/2023	**Oculus Pentacam Axl** Ref 70100, CE 0123	**OCULUS OPTIKGERAETE GMBH** Wetzlar, Germany	There is a potential that optical devices with insufficient anti-reflective coating may lead to incorrect axial length measurements.
9/6/2023	**Oculus Myopia Master** Ref 68100, CE 0123	**OCULUS OPTIKGERAETE GMBH** Wetzlar, Germany	There is a potential that optical devices with insufficient anti-reflective coating may lead to incorrect axial length measurements.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Oculus Pentacam Axl Wave** UDI-DI; (01) 04049584025357	143 Units Nationwide including California	August 8, 2023, and prior
II	**Oculus Pentacam Axl** UDI-DI; (01) 04049584012333	364 Units Nationwide including California	August 8, 2023, and prior

II	**Oculus Myopia Master** UDI-DI; (01) 04049584026095	173 Units Nationwide including California	August 8, 2023, and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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