This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

# IMPACT-RESISTANCE CERTIFICATION

"The certifying official of the manufacturer or seller listed below hereby guarantees that the articles listed below have been tested pursuant to 21 CFR 801.410 and are impact-resistant within the meaning of that section. Impact-resistant lenses are not unbreakable or shatterproof. Records of testing will be maintained for a period of three (3) years from the date of shipment, and copies will be forwarded to FDA upon request."

Certifying Official Signature: _____

Certifying Official Name & Title: _____

Manufacturer/Seller: _____

Address: _____

City, State: _____

Country, Mail or Zip Code: _____

## Articles tested for impact-resistance:

_____

_____

_____

_____