Addendum to Patient Information Leaflet for the ARTIFICIAL*IRIS* for Patients residing in Australia

Dear patient,
This Addendum to Patient Information Leaflet for Artificial Iris is to provide additional information with respect to the new regulation EP13A.3 of Therapeutic Goods Administration (TGA), Australia.

FOR WHICH ARTIFIAL IRIS MODELS MANUFACTURED BY HUMANOPTICS HOLDING AG IS THIS PATIENT INFORMATION INTENDED FOR?

ARTIFICIAL***IRIS*** with Fiber
ARTIFICIAL***IRIS*** Fiber Free

INTENDED PERFORMANCE OF ARTIFICIAL IRIS

The ARTIFICIAL***IRIS*** functions as an iris prosthesis. It has a fixed aperture of 3.35 mm, with an opaque perimeter and a black posterior surface to absorb light completely, reducing photic phenomena. The device closely mimics the appearance of the natural iris and at the same time reduces the symptoms associated with aniridia. The small central aperture might increase visual acuity, depth of field, and contrast sensitivity (pinhole effect).

THE MATERIALS AND SUBSTANCES INCLUDED IN THE DEVICE

ARTIFICIAL***IRIS*** contains no manufacturing residuals that could pose a risk to the patient.

REPORTING OF SERIOUS INCIDENTS

If a severe adverse event occurs, the doctor must report it to the national / local authorized representative, distributor if sold from a distributor and the manufacturer HumanOptics by calling 49 (0) 9131 50 66 5-0 or via email to mail@humanoptics.com and as well as to the Therapeutic Goods Administration (TGA). Their website is https://www.tga.gov.au/