ADVERSE INCIDENT NOTIFICATION FORM - IOL DEFECTS

Office use: / Centre:

Intruction: Where check boxes ☐ are provided, check (√) one or more boxes. Where radio buttons ◉ are provided, check (√) one box only.

All health care providers who noted defects on an intraocular lens either before, during or after IOL implantation are encouraged to report to the IOL Defects On-line Notification initiated and coordinated by the National Eye Databse (NED). NED is a web-based registry on eye diseases, sponsored by the MOH and Malaysian Society of Ophthalmology. The report will be monitored and reported to the Medical Device Devision, MOH for further investigation. A periodic report will also be available on NED website.

* **i) Date of notification:** / / (dd/mm/yyyy)

Section A: Description of an Adverse Event

1. Date of diagnosis of IOL defect: (dd/mm/yyyy)	/ /	**2. Date of IOL implantation:** (dd/mm/yyyy)	/ / ☐ Estimated year (If the exact date is not known, please enter 30/06/yyyy and tick the Estimated year checkbox)

3. Type of incident: *

☐ IOL Opacification ☐ Fine deposits on optic ☐ Early cataract formation subsequent to phakic IOL implantation ☐ Failure of IOL injector
☐ Crack on optic ☐ Fracture or detachment of haptic(s) ☐ Incorrect labeling of IOL, including IOL power ☐ Others, specify: .....
☐ Lines on optic

4. Patient characteristics:

*	**a. Age of patient at implantation:**		**b. Current age:** *		**c. Gender:** * ◉ Male ◉ Female
*	**d. Ocular co-morbidity:**	☐ Glaucoma ☐ Uveitis ☐ Diabetic retinopathy ☐ Others, specify:			
*	**e. Systemic co-morbidity:**	☐ Diabetes mellitus ☐ Renal failure ☐ Hypercalcemia ☐ Others, specify:			
*	**f. Previous ocular surgery (besides cataract surgery):**	☐ Glaucoma surgery ☐ Vitreoretinal surgery ☐ Others, specify:			

Section B: Action Taken

1. Action taken: *

☐ None
☐ Monitoring
☐ Explantation of IOL →

*	**a. Date of explantation:**	/ / (dd/mm/yyyy)
*	**b. Replaced with new IOL?**	◉ Yes ◉ No
*	**c. Reason(s) for explantation:**	☐ Decrease in best corrected visual acuity ☐ Significant halos / glare / starbursts ☐ Significant irregular astigmatism induced ☐ Diplopia, or other significant visual disturbances ☐ IOL dislocation ☐ IOL opacification ☐ IOL defect ☐ Others, specify:

Section C: Outcome of Incident

1. Outcome: *

☐ Financial loss - Hospital or individual *(e.g. the need to buy new IOL and have another operation)*
☐ Distress to the patient
☐ Complaint from public
☐ Non-significant

Section D: Details of IOL

1. IOL company: *

◉ Alcon ◉ Medennium ◉ Freedom IOL ◉ The Vision Membrane phakic IOL ◉ Not known
◉ Hoya ◉ Ophtec ◉ AMO ◉ The PRL Phakic Refractive Lens
◉ ERILENS ◉ Oll Intracular Lenses ◉ Tekia Inc ◉ Eyeonics
◉ Lenstec ◉ Corneal ◉ Staar ◉ GEL-MED International
◉ Others, specify: .....

2. IOL model:

3i. IOL type: ◉ Foldable ◉ Non foldable ◉ Not known

3ii. IOL material: ◉ Acrysoft hydrophobic ◉ Acrysoft hydrophilic ◉ Silicon ◉ PMMA ◉ Not known

4. Lot No. / Serial No.:

5. IOL Expired date: (if available) / /

6. Distributor company:

a. Name:	
b. Contact address:	
c. Email:	
d. Contact no.:	- H/P: -

Section E: Reporting Person

1. Reporting person's name:	*	
2. Position:	*	◉ Doctor ◉ Nurse ◉ Medical Assistant ◉ Others, specify:
3. Name of facility:	*	
4. Email:	*	
5. Contact no:	*	- H/P: -

Thank you for reporting an adverse incident concerning an IOL. Our NED manager will be contacting you shortly.