COM-ID:	COM-20_____-_____

Data privacy: All (personal) data will be treated confidentially. However, in the context of processing the complaint, it may be necessary to disclose your identity and / or the content of the complaint to official bodies (authorities, notified bodies) and to conduct a formal investigation due to reporting obligations. Should such disclosure be necessary, it will only be made to the person(s) who have a compelling need to know your identity or the details and nature of the complaint.

Please return the completed and signed pages ("To be completed by complainant:") to IOP GmbH.

Fax:	+49 (0) 511 2204 2589
E-Mail:	complaint@implandata.com
Postanschrift:	Implandata Ophthalmic Products GmbH QM&RA department Kokenstrasse 5 30159 Hannover Germany

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To be completed by complainant:

1.) Are you directly affected by the complaint?	
☐ Yes, as [1)] ☐ Patient ☐ User (Healthcare professional) ☐ Third Party (customer)	☐ No, on the behalf of a complainant [1/2)]
[1)] Contact details of complainant (if applicable)	
Company / institute	
First, last name / Patient-ID:	
Street, house no.:	
Post code, City:	
Country:	
Telephone:	
Mobile:	
Fax:	
E-Mail adress:	
[2)] Contact details of the person whom is reporting on the behalf of a complainant (if applicable)	
Company / institute	
First, last name:	

COM-ID:	COM-20_____-_____

Street, house no.:	
Post code, City:	
Country:	
Telephone:	
Mobile:	
Fax:	
E-Mail adress:	

2a.) Are you *currently* participating in a clincal trail of IOP GmbH?

☐ Yes, as ☐ No

☐ Participant (Patient)

☐ Study support (Healthcare professional, study staff)

2b.) Have you *previously* participated as a participant (patient) in a clinical trial of IOP GmbH?

☐ Yes ☐ No

3.) Which product is affected by the complaint? (Serial / UDI no. if known)

Reader device: - Patient - User - Third party	☐ Reader device	**Serial no.:**	
		UDI no.:	
	☐ Charger	**Serial no.:**	
	☐ User manual		
Reader device: - User - Third party	☐ Key module	**Serial no.:**	
	☐ Cable antenna	**Serial no.:**	
Implant: - User - Third party	☐ IO	**Serial no.:**	
		UDI no.:	
	☐ IO/KP	**Serial no.:**	
		UDI no.:	
	☐ SC	**Serial no.:**	
		UDI no.:	

COM-ID:	COM-20_____-_____

Surgical accessories: - User - Third party	☐ Injector	**Serial no.:**	
		UDI no.:	
	☐ Silicon paddings	**Serial no.:**	
		UDI no.:	
User manual: - User - Third party	☐ Implant ☐ IO ☐ IO/KP ☐ SC ☐ Injector		

4.) What is the reason for your complaint? (short description)

COM-ID:	COM-20_____-_____

5.) Have measures already been taken? If yes, which ones? (short description)

6.) When did the reason for the complaint occur? (Date)

7.) Where did the reason for the complaint occur? (Location)

Date

SIgnature of complainant / reporting person

COM-ID:	COM-20_____-_____

To be completed by IOP GmbH:

Complaint reported on (date)**:**		
Complaint reported by:	☐ Patient ☐ User (Healthcare professional) ☐ Third party (Customer, person in order) ☐ IOP GmbH employee (name):	
Complaint reported via:	☐ Fax ☐ Telephone ☐ personal conversation ☐ Mail ☐ E-Mail ☐ complaint@implandata.com ☐ service@implandata.com ☐ employee e-mail-account ☐ Other: @implandata.com	
Type of complaint:	☐ Product complaint ☐ Technical Support ☐ Incident ☐ Implantation procedure ☐ (current) Clinical trial ☐ Device deficiency ☐ Adverse Event (SAE) ☐ Other:	
Risk assessment:	☐ non-serious ☐ serious[3)]	
[3)] Information of PRRC:	☐ yes [3)] ☐ n.a.	
	Date:	
	Contact person:	
	Forwarding via:	☐ E-Mail ☐ Telephone ☐ Meeting
Forwarding to / registration and processing of the complaint in the responsible department:	**Department:**	
	Contact person:	
	Forwarding via:	☐ E-Mail ☐ Telephone ☐ Meeting
	Registration as:	
	[3)] Obligation to report:	☐ yes (authorithy / date): ☐ n.a. / ☐ no (justification):
	[3)] Corrective actions (in the market)**:**	☐ yes (see also annex) ☐ no ☐ n.a. ☐ FSN ☐ FSCA ☐ Product recall
	Completion date:	
Comments:		
Closure by QM&RA department / PRRC (date / signature)**:**		