**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 |

|  |  |  |  |
| --- | --- | --- | --- |
| **To be completed by complainant:** | | | |
| **1.) Are you directly affected by the complaint?** | | | |
| Yes, as 1) | | | No, on the behalf of a complainant 1/2) |
|  | Patient | | |
|  | User (Healthcare professional) | | |
|  | Third Party (customer) | | |
| **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:** | |  | |
| **Street, house no.:** | |  | |
| **Post code, City:** | |  | |
| **Country:** | |  | |
| **Telephone:** | |  | |
| **Mobile:** | |  | |
| **Fax:** | |  | |
| **E-Mail adress:** | |  | |

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| --- | --- | --- | --- |
| **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.:** |  |
| **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) |
|  |

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

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| --- |
| **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 |

| **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 | | | | | | serious3) | | | | | | | | | | | | |
| **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)**:** |  | | | | | | | | | | | | | | | | | | |