**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 GmbHQM&RA departmentKokenstrasse 530159 HannoverGermany |

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| --- |
| **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 |

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| --- |
| **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) |
|       |

|  |
| --- |
| **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)**:** |       |