Instruction:
Please fill in this report and send it by e-mail to the address below. **Make sure not to submit any identification of patient/end user if they are EU citizens**. If a product return is requested, return the product (and its package, if available) clearly marked with the assigned RGA number to ATOS MEDICAL AB for investigation. Thank you for your cooperation!

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| --- | --- | --- |
| **ATOS MEDICAL AB** |  | Complaint Registration number/Return Goods authorization numberfilled in by ATOS MEDICAL AB:**RGA no**.       |
| Att: Complaint InvestigatorKraftgatan 8SE-242 35 HörbySWEDEN | Telephone: Int.+46 (0)415-198 00Telefax: Int.+46 (0)415-198 98Web: www.atosmedical.com Email: **complaint.se@atosmedical.com** |

 Reporter contact information

|  |  |
| --- | --- |
| Distributor or subsidiary:      | Complainant:       |
| Contact person:      | Hospital (if applicable):       |
| Address:     E-mail:      | Address:      E-mail:       |
| Country:       | Country:       |
| Tel:       | Tel:       | MBI No (US only):        |

Customer relation

|  |  |
| --- | --- |
| Warranty product given to customer? **[ ]  Yes** **[ ]  No** | Is follow-up requested by customer? **[ ]  Yes** **[ ]  No** |

Product

|  |  |  |
| --- | --- | --- |
| Ref No:       | Product name:       | Lot or Serial No:       |
| Manufacturer: Atos Medical AB **[ ]**  Other (3PP): **[ ]**       | Complaint Quantity:       |

Event info

NOTE! Complaints must be forwarded to ATOS MEDICAL AB without delay, due to vigilance reporting requirements.

|  |  |
| --- | --- |
| Date when **company representative** was made aware of event (by mail, phone call, personal meeting etc): |       |
| Date when the event occurred (per information received from customer):  |       |
| Country where the event happened: |       |

|  |  |
| --- | --- |
| Did the event lead to death or serious injury? **[ ]  No** **[ ]  Yes** (Describe in detail below)Was medical intervention required? **[ ]  No** **[ ]  Yes** (Describe in detail below)Any residual adverse effect on patient? **[ ]  No** **[ ]  Yes** (Describe in detail below) | Patient injured, frightened or experienced discomfort [ ] (Describe in detail below) or Product complaint only [ ]  |
| How long has the **actual** product been used by patient?       | Has the product been used according to instructions? **[ ]  Yes** **[ ]  No** |
| Has the patient/user experienced this problem previously?**[ ]  Yes**, if so when?      **[ ]  No** | Is the product available for examination? **[ ]  Yes** **[ ]  No** Are products from same lot/carton available? **[ ]  Yes** **[ ]  No** |
| Have other products/medicines been used together with the product?If so, please list here       |

Event description

Please include a detailed description of what is considered wrong with the product and/or what happened to the patient.

Feel free to uses as many pages as necessary. The more information the better.

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| --- |
|       |
| Initial reporter within organization:       |