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!

|  |  |  |
| --- | --- | --- |
| **ATOS MEDICAL AB** |  | Complaint Registration number/  Return Goods authorization number  filled in by ATOS MEDICAL AB:  **RGA no**. |
| Att: Complaint Investigator  Kraftgatan 8  SE-242 35 Hörby  SWEDEN | Telephone: Int.+46 (0)415-198 00  Telefax: Int.+46 (0)415-198 98  Web: 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.

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