**ADVERSE EFFECTS REPORTING FORM**

Registration number....................................

Date..............................................................

Type of report

¨ Initially ¨ Tracking

1. User details

|  |  |  |
| --- | --- | --- |
| Name | Sex | Age |
|  |  |  |
| Address | | |
| Telephone number | | |

1. Details about the device used

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Device name/type | Device Serial/No | Daily duration of use | Total duration of use | The therapeutic indication |
|  |  |  |  |  |
|  |  |  |  |  |

1. Concomitantly administered medication

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Product name | Concentration | Frequency of administration | Route of administration | Duration of treatment | The therapeutic indication |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. Details of the adverse event

|  |
| --- |
| Start and stop date of treatment, description of the effects and the causal relationship with the SaltMed device |
|  |
|  |
|  |
|  |
|  |
|  |
|  |

1. Relevant medical history / associated diseases / allergies

|  |  |  |
| --- | --- | --- |
| Diagnosis or signs/symptoms | Start date | Stop date |
|  |  | ¨In progress |
|  |  | ¨In progress |
|  |  | ¨In progress |

1. Details about the person reporting the adverse event

|  |
| --- |
| Name: |
| Contact details ( *tel, email* ): |
| The relationship with the user ( *doctor, pharmacist , parent , user* ): |

1. Follow-up 8. Information about the attending physician

|  |  |
| --- | --- |
| We may contact you in the future  ¨ Yes ¨ No | Name |
| Can we contact your doctor?  ¨ Yes. ¨ No | Specialization/Medical unit |
|  | Contact details |

1. Completed by

|  |
| --- |
| Name: |
| Date: |
| Signature : |