# **UrCon**

# Risk Management Document - Controlled document

**Disclaimer:** This document, and the technologies it describes, is the property of Aalborg University. This document shall not be reproduced or used without explicit permission of an authorized company official.

**Note:** Risk analysis can be seen in RiskManagementDocument.xlsx

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision Control** | | | |
| Revision | Revised by | Revision date | Change Description |
| 0.1 | Maja Husum | 05/04/2024 | First Version of risk management document |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Authorized by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Scope and intended use

This document has the purpose of identifying hazards and hazardous situations for the application UrCon. UrCon is intended to support the users use of UCon. The support will be achieved through a bladder diary, visualized stimulation data and notifications. The application is further described in the project report (insert file name). The risk analysis of the system will be conducted according to the RiskManagementPlan.docx. The analysis will be divided into two perspectives: Usability risk and Software risk. Usability risk will focus on what the user can do wrong and failures they can cause. The software risk focuses on possible failures and incompatibilities within the system. The steps described in the RiskManagementPlan.docx will be executed in the sections below.

## Responsibility

The actors responsible for risk management is a group of students from Aalborg University. These students have, by lectures and individual study, acquired theoretical knowledge and experience in risk management. Relevant documents for risk management will be reviewed by the same group of students.

## Definitions

Terms and definitions are defined in DS/EN ISO14971.

## Identification of parties performing the Risk Analysis

Parties of performing risk analysis, is the same group of students defined in section 2.

## Software classification

UrCon is classified as class A using the software classification defined in EN IEC 62304:2006/AMD1:2015