UDecide

INTENDED PURPOSE  
DOCUMENT REFERENCE NUMBER: UD-IP  
  
DATE: 11-05-2021  
 REVISION NUMBER: 1

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SCOPE: This document contains the intended purpose for the UDecide system.

REFERENCES:

REVISION HISTORY:

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| --- | --- | --- | --- |
| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
| 1.0 | Sofie Bjørn | 11-05-2021 | First edition in technical documentation. |
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APPROVAL:

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|  | *Name and job function* | *Signature* | *Date* |
| *Author:* |  | | |
| *Reviewer:* |  | | |
| *Independent reviewer:* |  | | |

To conform with the regulatory requirements in the MDR, an intended purpose for the UDecide decision support system has been defined. The intended purpose is as follows:

The UDecide system is a decision support system, intended for medical purpose, by supporting the OAB specialist in a cost-benefit assessment during the consultation. The assessment is conducted when choosing a stimulation paradigm in order to treat OAB patients with DGN stimulation to minimize the patient's OAB symptoms. Additionally, UDecide is intended to be used in combination with the UCon product, whereas a precondition for using UDecide is, that neurostimulation with UCon is considered as a treatment tool. Furthermore, the decision support from the UDecide system is not intended for use at children.