| **Design & Development Plan** | xxx, Version 1 |
|---|---|
| Scope | The scope of this Design & Development Plan is the development of xxxx |
| General requirements | The general requirements and the approach to design control, including design stages, are described in SOP Design Control. |
| Organization | All responsibilities and the functions required, as well as the required competences, are described in SOP Design Control. For this specific product development, the following project team members were identified:<br>• R&D will be represented by xxxx<br>• QA/RA will be represented by xxxx<br>• Production will be represented by xxxx<br>• Purchasing, if needed, will be represented by xxxx<br>• Sales will be represented by xxxx<br>• Marketing will be represented by xxxx<br>• Medical will be represented by xxxx<br>Approval & signature requirements, including authorizations, are given in SOP Design Control. |
| Communication, interfaces and resources | To ensure the communication needed, the following Design review meetings will be held:<br>• Design Input review<br>• Design Verification review<br>• Final Design review<br>A PMS/PMCF review will held approx. xxxx months after Final Design review<br>There are no specific communication requirements to this project.<br>Existing resources (headcount and infrastructure) are deemed sufficient. |
| References | xxxx |

| **Tasks** | **Responsible person** | **Time plan / Date of completion** |
|---|---|---|
| Regulatory Strategy | xxxx | - |
| Risk Management Plan | xxxx | - |
| Usability Plan | xxxx | - |
| Design Input | xxxx | - |
| **Design Input Review Report** | xxxx | xxxx |
| Design Output Documents | xxxx | - |
| Design V&V Plan | xxxx | - |
| Design Verification Protocol | xxxx | - |
| Design Verification Report | xxxx | - |
| Biocompatibility testing | xxxx | - |
| Packaging & Transport Sterile Barrier System | xxxx | - |
| Labelling | xxxx | - |
| Sterilization validation | xxxx | - |
| Shelf-life testing | xxxx | - |
| Stability testing | xxxx | - |
| **Design Verification Review Report** | xxxx | xxxx |

| Tasks | Responsible person | Time plan / Date of completion |
|---|---|---|
| Design Validation Protocol | XXXX | - |
| Design Validation Report | XXXX | - |
| Usability Validation Plan | XXXX | - |
| Usability Validation Report | XXXX | - |
| Design V&V Report (including traceability matrix) | XXXX | - |
| Clinical Testing | XXXX | - |
| Clinical Evaluation | XXXX | - |
| Design Transfer | XXXX | - |
| Risk Management Report | XXXX | - |
| DHF Review | XXXX | - |
| **Final Design Review Report** | XXXX | XXXX |
| PMS/PMCF Review | XXXX | XXXX |

| Approval | |
|---|---|
| R&D | *(name / date / signature)* |
| QA/RA | (*name / date / signature)* |