Plan for Post-Market Clinical Follow-Up (as per (EU) 217/745 MDR)

Background

Article 61.11 and Annex XIV Part B of (EU) 217/745 (MDR) requires manufacturers of medical devices to plan and report Post-Market Clinical Follow-Up (PMCF). This PMCF Plan was written as per SOP PMS *xxxx* and PMS Plan *xxx.*

Purpose

This PMCF Plan was written for the product family *xxxx* identified with Basic UDI-DI *xxxx* as listed in the list of CE-marked devices *xxxx.* It updates the previous PMCF Plan *xxxx* dated *xxxx.*

The product family *xxxx* is classified as a medical device class *xx* following rule *xx* of Annex VIII (EU) 2017/745 (MDR).

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1. PMCF objectives and methods

The product family *xxxx* was introduced to the European market in the year *xxx.*

The current technical documentation *xxx* includes

- relevant information of previous and similar products in the European and international markets (STED section 1.2),
- standards, regulations (including, if applicable, common specifications) and relevant guidance documents (STED section 4.3),
- residual risks from usage, design and benefit-risk analysis (STED section 5), and
- clinical benefits (STED section 6.1).

Within the clinical evaluation report *xxxx* it was concluded that PMCF will be required. (*PMCF especially may be needed if clinical evidence was provided via the equivalency route, introduction of new technical features/interactions, approaching new markets, and/or changed clinical regimes/habits, changes in patient population or healthcare systems…).*

The objectives of the PMCF activities are

- *Xxx*
- *(Describe the detailed objectives to be addressed by PMCF in accordance with the results of clinical evaluation report.*
- *Objectives are, for example, confirming the safety and performance of the device throughout its expected lifetime, identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, identifying and analysing emergent risks on the basis of factual evidence, ensuring the continued acceptability of the benefit-risk ratio, and identifying possible systematic misuse or off-label use of the device.)*

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Therefore the PMCF activities planned will, by proactively collecting continuous clinical data, further evaluate the safety and performance of the product family xxxx, especially with respect to the

- sections xxx from the clinical evaluation report xxxx and
- section xxxx of risk management report xxx.

For conducting the PMCF, the following method was identified:

- *Xxxx (describe the method(s) chosen for gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data*
- *like PMCF studies, questionnaires or clinical observations, evaluation of regional/national/international registries*,
- *Xxxx*.

This method is deemed justified as

- *xxxxx*
- *(give rationales for the methods selected).*

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2. PMCF specifics

The PMCF will be conducted under consideration of the following specifics:

- *Xxxx*
- *(give details, like references to studies, selected registries, user groups,*
- *Time plans including endpoints and justifications (in relation to the expected lifetime of the product),*
- *Applied standards, guidelines, regulations for conducting PMCF*
- *Roles and responsibilities for conducting the PMCF,*
- *monitoring and control measures needed during execution of PMCF,*
- *sampling plans,*
- *raw data recording,*
- *plan for data analysis of the clinical data collected,*
- *plan for drawing conclusions.*
- *One may reference supplemental protocols or plans.*

3. References

- SOP PMS xxx
- PMS Plan xxx
- PMCF Plan xxx
- List of CE marked devices xxxx
- Technical Documentation (STED) xxxxx
- Risk Management Report xxxx
- Clinical Evaluation Report xxxx
- Periodic Safety Update Report (PSUR) xxxx
- Summary of Safety and Clinical Performance (SSCP) xxxx
- IFU xxxx

Approvals

Medical Expert: _____ (Name, Date, Signature)

Quality Management: _____ (Name, Date, Signature)

Regulatory Affairs: _____ (Name, Date, Signature)

Product Management: _____ (Name, Date, Signature)