PMCF Plan Template as per Medical Device
Regulation (EU) 2017/745 (MDR) part B of Annex XIV

PMCF plan number:	PMCF plan date:	PMCF plan version:

REVISION HISTORY			
Rev	Revision date	Description of Change	Revised by

SECTION A. MANUFACTURER CONTACT DETAILS
Legal manufacturers name:
Person responsible for regulatory compliance:
Contact person for PMCF
E-mail:

SECTION B. MEDICAL DEVICE DESCRIPTION AND SPECIFICATION
Product or trade name:
List and description of any variants Wand/or configurations covered by this plan:

SECTION C. ACTIVITIES RELATED TO PMCF: GENERAL AND SPECIFIC METHODS AND PROCEDURES *(tick all that apply and complete a different subsection for each e.g C.1 C.2, …)*	
☐	Device registry
☐	PMCF studies
☐	Real-world evidence
☐	Surveys
☐	A review of relevant retrospective data from patients previously exposed to the device.
☐	The extended follow-up of patients enrolled in premarket investigations
☐	Other (explain)

SECTION C. 1 DESCRIPTION OF ACTIVITY		Details / explanation & Justifications
Clearly stated research question		
Objective *(tick all that apply)*		
☐	Confirming the safety of the device throughout its expected lifetime	
☐	Confirming the performance of the device throughout its expected lifetime	
☐	Identifying previously unknown side-effects (related to the procedures or to the medical devices)	
☐	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	
☐	Identifying possible systematic misuse or off-label use of the device, with a view to verify that the intended purpose is correct.	
☐	An analysis of a larger study population – (e.g. more health centres, more countries, increase in diversity of age / race)	
Describe the different procedures which will be used as part of PMCF		
☐	Survey from health care professional	(attached a copy of the planned survey to this plan)
☐	Survey from patients/users	(attached a copy of the planned survey to this plan)
☐	Collecting data in registries	
☐	Review of case reports which may reveal misuse or off-label use	
☐	Screening of scientific literature and other sources of clinical data	
☐	Post-market studies	

The clinical investigation plan/study plan should identify and where needed justify at a minimum: *(The points below may not all apply to a retrospective data review)*	Justifications
• the study population (corresponding to the CE-mark scope)	
• inclusion/exclusion criteria;	
• rational and justification of the chosen study design including use of controls/control groups (where relevant; randomised or not)	
• the selection of sites and investigators;	
• related study endpoints	
• statistical considerations	
• the number of subjects involved	
• the duration of patient follow-up	
• the data to be collected	
• the analysis plan including any interim reporting where appropriate to ensure continuous risk management based on clinical data;	

• procedures/criteria for early study termination	
• ethical considerations	
• methods of quality control of data where appropriate	

SECTION C. 2 (IF APPLICABLE) *(copy table C1 below and complete)*	Details / explanation
Clearly stated research question	

SECTION D. REFERENCE TO THE RELEVANT PARTS OF THE TECHNICAL DOCUMENTATION
Clinical Evaluation Report (date and version)
Risk Management File (date and version)

SECTION E. EVALUATION OF CLINICAL DATA RELATING TO EQUIVALENT OR SIMILAR DEVICES
The manufacturer shall gather in this section information regarding equivalent / similar devices for which clinical data will be further evaluated and presented in the PMCF report. Please note that PMCF data intended to demonstrate continuing safety and performance should be sourced from the device under evaluation. Data from equivalent or similar devices may be used, for example to update the information relating to the state of the art, to identify and further assess relevant safety outcomes etc. The selected devices shall be consistent throughout the technical documentation submitted for CE approval

SECTION F. REFERENCE TO ANY APPLICABLE COMMON SPECIFICATION(S), HARMONIZED STANDARD(S) OR APPLICABLE GUIDANCE DOCUMENT(S)
Common specification(s) to comply with, if applicable: (Title, date and version) Harmonised standards to apply, if applicable (Title, date and version) Guidance on PMCF, if applicable Regulatory or Specific guidance identifying benchmark requirements for the device type , if applicable

SECTION G. – ESTIMATED DATE OF THE PMCF EVALUATION REPORT
When the manufacturer plans to have the first report. The timelines shall be defined quarterly or at least yearly.

MANUFACTURERS APPROVAL OF THE PMCF PLAN	
Name:	Signature:
Position:	Date: