Clinical Evaluation Plan

Product n ame:	Air Compressi on Therapy System
Model:	AC mechanical model: FO3001M,FO3001BM,FO3001EM,F03006,FO3001M-1; AC electronic model: FO3001,FO3001B,FO3001C,FO3001D,FO3001E,FO3001K,FO3008,FO3012,FO3001F,FO3001-2,FO3001-3,FO3001D-1;
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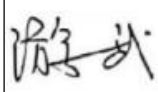
Role	**Signature**	**Date**
Prepared by		2023-03-07
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Revision Record

Revision history				
No.	**Version**	**Author**	**Date**	**Description**
1	V1.0	You wu	2023-03-10	First issue

Background Information, Reference, and Device under Evaluation, and Classification

1.1 Reference

• MDCG 2020-5: Clinical Evaluation — Equivalence. A guide for manufacturers and notified bodies
• MDCG 2020-6: Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
• MDCG 2020-13: Clinical evaluation assessment report template
• REGULATION (EU) 2017/745 REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017
• MEDDEV 2.7/1 revision 4 - Clinical evaluation: A guide for manufacturers and notified bodies
• IMDRF MDCE WG/N56FINAL:2019-Clinical Evaluation

1.2 Device under Evaluation

No.	Product Name	Model
1	Air Compression Therapy System	FO3001, FO3008, FO3001B, FO3001C

1.3 Device Operation Principle

Air Compression Therapy System consists of air pressure sensor, air pump, sleeves etc working together as one unit. The air pump is connected to the dedicated sleeves via a series of hoses. The compression massage direction is from limb end to body center by inflating the air chambers sequentially and then deflating as one cycle, the pressure can be adjusted to avoid any discomfort to the patient. The sleeve works under the action of sensor and microprocessor, Air Compression Therapy System has a sequential squeezing from distal to proximal, thus help to improve the circulation of blood and lymph, and to prevent the DVT and relieve lymph edema.

1.4 Classification

Class IIa, According to MDR Annex VIII, Rule 9

1.5 Clinical Evaluation Route

1.5.1 Rationale why clinical trial is unnecessary

The current technical level of the product is mature; the clinical safety and performance have been validated, and no clinical research will be conducted after the market. Therefore, based above-mentioned analysis, clinical trial is unnecessary.

1.5.2 Rationale why equivalence route is chosen

Equivalence route, since
1) There is sufficient clinical data of equivalent device to demonstrate conformity of the device with the relevant safety and performance requirements.
2) Air Compression Therapy System is the proven technology and is well accepted by the medical community.

1. Identification of the relevant general safety and performance requirements that require support from relevant clinical data

The general safety and performance requirements that require support from relevant data are listed below:

CHAPTER I GENERAL REQUIREMENTS OF GSPR:

GSPR 1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high.

GSPR 8. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

2. Device description

3.1 Specification of the intended purpose of the device

3.1.1 Intended use

The product is indicated for use by medical professionals and patient at home, who are under medical supervision, reducing swelling and preventing thrombosis in the lower extremities or treatment of truncal or arm breast cancer-related lymphedema, such as: Primary lymphedema, edema following trauma and sport injures, post-immobilization edema, Venous insufficiencies, Lymphedema.

The system can be used at home or in hospital, to patients who are over 18 years old.

3.2 Technical Specifications

3.2.1 Clinical benefits and performance to be evaluated

ITEM	TECHNICAL INDEX
Number of chambers	4 chambers
Machine size	240 x 200 x 120mm
Weight (with accessories)	2.22kg
Control way	LED touch
Treatment time	10-60 minutes
Treatment pressure	30~250mmHg
Pressure error	<15%
Cycle time	85s~133s, ± Is

Treatment modes	6 modes
Chamber Setting	Settable
Input voltage	AC 220-240V, 50-60Hz
Power consumption	65VA
Noise level	<55dB
Protection against electric shock	Class II, Type BF Applied Part
Mode of operation	Continuous operation
Degree of waterproof	IP21
Product life	5 years
Operating environment condition	+10℃ - +40 ° C, 10% - 95%RH
	86kPa-106kPa
Storage & Transport environment condition	-40 C - +70 C, 10% -100%RH
	50kPa-106kPa
Leg Sleeve size	L: 100 x74cm (T02-04)
	XL: 110 x70cm (T03-04)
	XXXL: 125 x76cm (T05-04)
Extension part	Width 10cm (for leg sleeve)

3. State of the art evaluation

To keep update the evaluation of the state of the art, clinical evaluator should collect data listed below:

- literatures related
- alternative options
- data from PMCF, related standards

The evaluator should update the state of the art evaluation by analyzing the related literatures, data from PMCF, standards and CS etc. every two years.

4. Evaluation strategies and data used for evaluation

Evaluation strategies and data to be used for clinical performance and technical performance are described in the following table.

Evaluatio n items	Data to be used	Data source
Technical performance	Related verification and test of the evaluated device	Derived from the evaluated device
Clinical performance and safety	Literatures and reported problems	Pubmed, Springer and ScienceDirect; FDA TPLC - Total Product Life Cycle NMPA website

Evaluatio n items	Data to be used	Data source
State of the art	Literatures of the benchmark and similar devices, guideline, practices etc.	Pubmed, Springer and ScienceDirect, and manufacturer

5. Clinical evaluation contents and plan

SN	Task	Complete Date
1	Ide ntify available cli ni cal data	2023.03
2	Literature search protocol	2023.03
3	Literature search and literature search report	2023.03
4	State of the art evaluati on	2023.03
5	Demon strati on of equivale nee	2023.03
6	Cli ni cal evaluati on report	2023.04
7	PMS pla n	2023.04
8	PMCF pla n	2023.04
9	Cli ni cal evaluati on report updati ng	2023.05

6. Specification of qualitative and quantitative aspects of clinical safety and performance

10.1 Pre-clinical Studies

Tests are performed in regard to biocompatibility, performance, usability with specified requirements. Evidence shall be provided.

10.2 Clinical data under state of the art

10.2.1 Common specifications

There is no common specification for the product.

10.2.2 Harmonized and other standards applied

Serial Number	Title
EN ISO 20417:2021	Medical devices - Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN SO 14971:2019+A11:2021	Medical devices — Application of risk management to medical devices

CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
EN 60601-1:2006+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021	Medical electrical equipment part 1: General requirements for safety 2:Collateral standard: Electromagnetic compatibility — requirements and test
EN 60601-1-6:2010 +A1:2015+A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices

10.2.3 Literature retrieval protocol

The retrieval should be developed and executed by persons with expertise in information retrieval, having due regard to the scope of the clinical evaluation set out by the manufacturer. The involvement of information retrieval experts will help to optimize literature retrieval to identify all relevant published literature.

1) **Objective**

The objective of this search was to prove the treatment is better than or at same level than the current mainstream technology.

2) **Database source**

Database source contains PubMed, Springer and ScienceDirect. PubMed remains the most popular search engine used to retrieve original studies, which contains journals more than 6000, mainly involving medical, biomedical, sciences and clinical core journals, updated every day, can get particular topic tracking, and return to around 5% of the peripheral related results (i.e., false positive), it is easy to search, and can be mixed and combined to search to meet the recall rate and accuracy rate. However, with possibly incomplete coverage of European Journals and comprehensiveness may not necessarily be guaranteed, so Springer and Elsevier ScienceDirect can be used as supplements. Springer contains electronic full-text of nearly 2,900 journals covering 13 disciplines, the system is a comprehensive database; in addition to medicine, there are other non-medical catalogues that may also include medicine-related journals. Elsevier ScienceDirect, the world's largest platform dedicated to peer-reviewed primary scientific and medical research, hosts more than 20 million pieces of content from over 4,600 journals and over 45,000 eBooks and receives more than 18 million visitors a month. Elsevier has continued to invest in ScienceDirect and integrate new remote access methods to give researchers the ability to easily use its tools when working from home, safe in the knowledge that they are doing so securely, and that their privacy and data are protected.

Source	**Online Location**

Source	Online Location
Medline/PubMed Resources	http://www.ncbi.nlm.nih.gov/sites/entrez
Springer	http://link.springer.com/
Elsevier ScienceDirect	https://www.sciencedirect.com/

3) Search information

Date of search	Record date information
Name of person(s) undertaking the literature search	Record related information
Literature sources used to identify data:	PubMed, Springer, Elsevier ScienceDirect

4) Key words and search strategy

Since different data sources have corresponding unique characteristics, then we first list selectable key words and then carefully determine specific key words.

Table 1 Reference and Selectable Key Words

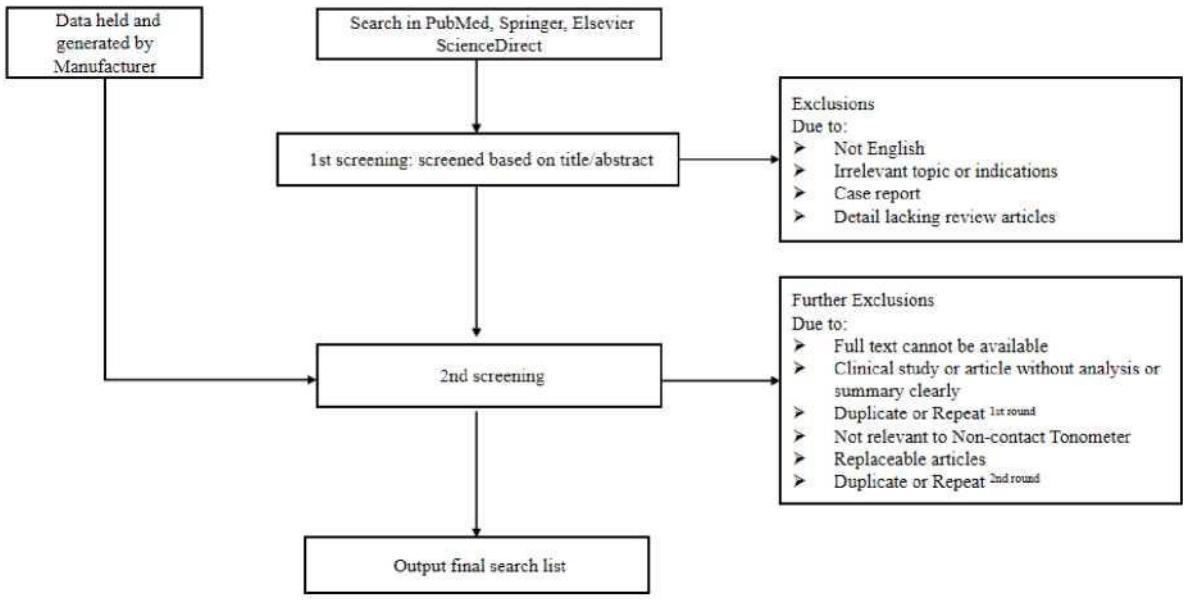
No.	Reference and selectable key word	Selection Reason
1	Air compression therapy	Name of target device, name of the device can include more possible available literatures
2	IPC for edema	For intended indication
3	IPC for DVT	For intended indication
4	IPC for lymphedema	For intended indication

Table 2 Specific Key Words of Difference Data sources

No.	Data source	Group	Key Word	Selection Reason
1	PubMed	1	Air compression therapy	No time limit, or other limitations, all fields
		2	IPC for edema	
		3	IPC for DVT	
		4	IPC for lymphedema	
2	Springer	1	Air compression therapy	Contain all words; not include preview-only content; no time limit
		2	IPC for edema	
		3	IPC for DVT	
		4	IPC for lymphedema	
3	Elsevier ScienceDirect	1	Air compression therapy	Open access & Open archive; no time limit, No time limit
		2	IPC for edema	
		3	IPC for DVT	

		4	IPC for lymphedema	

5) Inclusion and exclusion criteria



6) Strategies for addressing the potential for duplication of data across multiple publications

During 2nd screening as per inclusion and exclusion criteria,

Exclude those articles from same data source with different keywords and published in different multiple publications.

Exclude duplication of articles retrieved from different data sources and published across multiple publications.

7) Strategies for avoiding retrieving publications of data generated and already held by the manufacturer

Exclude duplication of articles which are generated and already held by the manufacturer.

9.2.4 Data collection plan

Step	Step description		Remark/Reason/Inclusion and exclusion criteria
1	Search in the databases	Targeted databases: PubMed, Springer, Elsevier ScienceDirect	PubMed remains the most popular search engine used to retrieve original studies, which contains journals more than 6000, mainly involving medical, biomedical, sciences and clinical core journals, updated every day. However, with possibly incomplete coverage of European Journals and comprehensiveness may not necessarily be guaranteed, so Springer and Elsevier ScienceDirect can be used as supplements. Springer contains

Step	Step description		Remark/Reason/Inclusion and exclusion criteria
			electronic full-text of nearly 2,900 journals covering 13 disciplines, the system is a comprehensive database; in addition to medicine, there are other non-medical catalogues that may also include medicine-related journals. Elsevier ScienceDirect, the world's largest platform dedicated to peer-reviewed primary scientific and medical research, hosts more than 20 million pieces of content from over 4,600 journals and over 45,000 eBooks and receives more than 18 million visitors a month. Elsevier has continued to invest in ScienceDirect and integrate new remote access methods to give researchers the ability to easily use its tools when working from home, safe in the knowledge that they are doing so securely, and that their privacy and data are protected.
2	1st screening: Based on title/abstract	Not English	Only article in English could be generally understood and accepted by the evaluator who is unable to speak or read articles in other language such as French, Spanish and so on.
		Irrelevant topic or indications	Targeted/Relevant topic: relevant to the disease management and treatment; relevant to targeted devices; other topics such as disease development and diagnosis are irrelevant;
		Case report	The number of cases included in the case report is too small to be representative.
		Detail lacking review articles	The literature only briefly describes the treatment methods and lacks specific details.
3	2nd screening	Full text cannot be available	Only article that can be available could be directly understood and analyzed by the evaluator to obtain more details.
		Clinical study or article without analysis or summary clearly	Specific information can only be obtained if the literature contains indications or clinical data.
		Duplicate or repeat 1st round	1) Exclude duplication of articles retrieved from the same data sources with different keywords and published across multiple publications; 2) Exclude duplication of articles retrieved from different data sources and published across multiple publications;
		Not relevant	Guideline or practices of specific indication shall be included

Step	Step description		Remark/Reason/Inclusion and exclusion criteria
		Replaceable article	The latest reports were used for reports of the same content at different times in the same organization or the same institution
		Duplicate or repeat 2nd round	Exclude duplication of articles which are generated and already held by the manufacturer
4	Output final search list		

9.2.5 Summary and appraisal of clinical Data

The purpose of undertaking appraisal of the data is to understand the merits and limitations of the clinical data. Each piece of data is appraised to determine its suitability to address questions about the medical device, and its contribution to demonstrating the safety, clinical performance and/or effectiveness of the device (including any specific claims about safety, clinical performance and/or effectiveness).

9.2.6 Data appraisal plan

The data needs to be assessed for its quality and its relevance to the device in question including its intended use (i.e. the data must be either generated for the device in question or for a comparable device). In addition, any reports or collations of data should contain sufficient information for the evaluator to be able to undertake a rational and objective assessment of the information and make a conclusion about its significance with respect to the safety, clinical performance and/or effectiveness of the device in question. Further appraisal needs to be undertaken to determine the contribution of each data subset to establishing the safety, clinical performance and/or effectiveness of the medical device. The evaluator should examine the methods used to generate/collect the data and assess the extent to which the observed effect (performance or safety outcome(s)) can be considered to be due to intervention with the medical device or due to confounding influences (e.g. natural course of the underlying medical condition, concomitant treatment(s)) or bias. The evaluator should also assess whether clinical data are collected in conformance with the applicable regulatory requirements or other relevant standards and whether clinical data are applicable to the population for which the marketing authorization is being sought.

Table 1 Appraisal Criteria for Suitability

Suitability Criteria	Description	Grading System	
Appropriate device	Were the data generated from the device in question?	D1=2 D2=1 D3=0	Actual device Comparable Other device
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1=2 A2=1 A3=0	Same use Minor deviation Major deviation
Appropriate patient	Were the data generated from a patient group	P1=2	Applicable

group	that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P2=1 P3=0	Limited Different population
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1=2 R2=1 R3=0	High quality Minor deficiencies Insufficient information

Criteria as presented in MEDDEV 2.7.1 Rev. 3-0 Appendix D

Table 2 Appraisal Criteria for Data Contribution

Data Contribution Criteria	Description	Grading System	
Data source type	Was the design of the study appropriate?	T1=1 T2=0	Yes No
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1=1 O2=0	Yes No
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1=1 F2=0	Yes No
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1=1 S2=0	Yes No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1=1 C2=0	Yes No

Criteria as presented in MEDDEV 2.7.1 Rev. 3-0 Appendix D

Details regarding considerations of data from various jurisdictions. (cited from IMDRF MDCE WG/N56FINAL:2019-Clinical Evaluation)

9.2.7 Appraisal result acceptable criteria

Same weighting level is assigned to three appraisal criteria, only when the coefficients of each appraisal condition >2, this clinical data was adopted.

9.2.8 Analysis of the clinical data searched of SOTA and then output the report

Evaluate if the clinical data on benefits and risks are acceptable for all medical conditions and target populations covered by the intended purpose and whether limitations need to be considered for some populations and/or medical conditions.

The current knowledge/ state of the art therefore needs to be identified and defined, possibly also relevant benchmark devices and medical alternatives available to the target population. Sufficient detail of the clinical background is needed so that the state of the art can be accurately characterised in terms of clinical performance, and clinical safety profile. The selection of clinical data that characterises the state of the art should be objective and not selective of data on the basis of being favourable for the device under evaluation. Information should be provided on alternative approaches that have been used or considered and their benefits and drawbacks. Deficiencies in current therapies should be identified from a critical and comprehensive review of relevant published literature. The literature review should demonstrate if the device addresses a significant gap in healthcare provision. Where there is

no such clinical need, the design solution needs to show an improved or at least equivalent benefit/risk profile compared to existing products or therapies.

Evaluate if the clinical data on benefits and risks are acceptable for all medical conditions and target populations covered by the intended purpose when compared with the current MEDDEV 2.7/1 revision 4 page 46 of 65 state of the art in the corresponding medical field and whether limitations need to be considered for some populations and/or medical conditions.

9.3 Clinical Data from Equivalent Device

A literature review is performed and focusing on equivalent products with regard to their clinical safety and performance to achieve essential information on the benefits and risks. The proposed level of clinical evidence should take into account the specification of methods to be used for examination of qualitative and quantitative aspects of clinical performance and clinical safety with clear reference to the determination of residual risks and side effects.

9.3.1 Clinical evaluation route

Assessment of safety and performance of the devices in scope is based on several data sources, including internal clinical studies, compliance with recognized standards, verification analyses as well as clinical data from the relevant published peer-reviewed clinical literature. So, The clinical evaluation is based on data related to device under evaluation and equivalent devices. Clinical data is from scientific literature of equivalent device and accuracy research of device under evaluation.

9.3.2 Comparison of Device under Evaluation and Equivalent Device

The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:

Technical:

the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;

Biological:

the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

Clinical:

the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

It shall be clearly demonstrated that we have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

9.3.3 Summary and appraisal of clinical Data

The purpose of undertaking appraisal of the data is to understand the merits and limitations of the clinical data. Each piece of data is appraised to determine its suitability to

address questions about the medical device, and its contribution to demonstrating the safety, clinical performance and/or effectiveness of the device (including any specific claims about safety, clinical performance and/or effectiveness).

9.3.4 Analysis of the clinical data

The goal of the analysis is to make a benefit/risk determination if the appraised data sets available for a medical device collectively demonstrate the safety, clinical performance and/or effectiveness of the device in relation to its intended use. The methods available for analysis of clinical data generally are either quantitative or/and qualitative. Given the context within which most medical devices are developed (i.e. limited need for clinical investigations because of incremental changes in device design and therefore high use of literature and experience data), it is most likely that qualitative (i.e. descriptive) methods will need to be used. Any evaluation criteria developed and assigned during the appraisal stage can be used to identify those sets of data which may be considered to be pivotal to the demonstration of the safety, clinical performance and/or effectiveness of the medical device, respectively. It may be useful to explore the results of the pivotal datasets, looking for consistency of results across particular device performance characteristics and identified risks. If the different datasets report similar outcomes, certainty about the clinical performance and/or effectiveness increases. If different results are observed across the datasets, it will be helpful to determine the reason for such differences. Regardless, all data sets should be included. As a final step the evaluator should consider the basis on which it can be demonstrated that the combined data confirm:

• the medical device performs as intended by the manufacturer;

• the medical device does not pose any undue safety concerns to either the recipient or end-user;

•any risks associated with the use of the device are acceptable when weighed against the benefits to the patient;

•compliance with the relevant GSPRs; and

•whether post market clinical follow up or post approval study is necessary.

7. Post-market Sources of Clinical Data

Based on the above conclusions, draw up the PMS plan and PMCF plan.

8. General considerations when updating the CER

Determine the frequency and timing of updates:

-when receives new information from PMS that has the potential to change the current evaluation;

If no such information is received, then:

-At least every two years

When updating the clinical evaluation, the evaluators should verify:

1) if the benefit/risk profile, undesirable side-effects (whether previously known or newly emerged) and risk mitigation measures are still

2) compatible with a high level of protection of health and safety and acceptable according to current knowledge/ the state of the art

3) correctly addressed in the information materials supplied by the manufacturer of the device correctly addressed by the manufacturer's current PMS plan

4) if existing claims are still justified

5) if new claims the manufacturer intends to use are justified

9. A specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side- effect

Use PMCF for examination of qualitative and quantitative aspect.

10. An indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device Assess whether the device meet requirement of conformity on clinical benefit.

The conclusion should be based on the following benefit-risk analysis: **Factor Clinical performance: clinical benefit with outcome parameter** Concerning question: does the clinical benefit achieve the expected result?

11. An indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable animal or human tissues, are to be addressed NA.

12. Clinical development plan

1) Clinical development plan and milestones

To determine the product safety-effectiveness/risk-benefit ratio remains acceptable:

A. Identify and specify applicable regulations and standards to be met,

B. Prove the technical performance through product verification and validation as per applicable regulations and standards, as well as relevant guidance (such as MDCG guidance),

13. Qualification of the responsible evaluators

Describe the person's educational background, work experience, qualifications, etc. All evaluators shall have no interests with the company.

14. Reference and related appendixes

List all references and appendixes