**Text: -**

# Scope of the Clinical Evaluation

1. 1: Introduction:

Provide details of Identification of devices covered by the clinical evaluation report, products, models, sizes, software versions, accessories, their proprietary names, code names assigned during device development. Whether the clinical evaluation is submitted to the MDD directive. Concise physical and chemical description, including materials. Whether the device incorporated medicinal substances (already on the market or new), tissues, or blood products. Mechanical and physicochemical characteristics; others (such as sterile vs. nonsterile, radioactivity etc.); Do not mention the class or classification of the device.

1. 2: Process Used to Perform Clinical Evaluation:

**Print the following** “This Clinical Evaluation follows the process described in Annex XIV, Part A of the MDR and summarized as:

* - Establish/update the clinical evaluation plan;
* - Identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic literature review;
* - Appraise all relevant clinical data by evaluating in terms of its suitability for establishing the safety and performance of the device;
* - Generate any new or additional clinical data needed to address outstanding issues, through properly designed clinical investigations in accordance with the clinical development plan; and
* - Analyze relevant clinical data to establish conclusions regarding the safety and clinical performance of the device, including its clinical benefits.”

**Table: -**

1. 3 Device Legal Manufacturer**:**

**table name: Details of the Legal Manufacturer**

**Columns: [-Manufacturer Name,**

**-Manufacturer Short Name (if not found then write manufacturer name same as it is),**

**-Manufacturer Address,**

**-Manufacturing Location]**

1. 4 Devices Covered by the CER:

**table name: Device Family**

**Columns: [-Device Family Name,**

**-Device Family Short Name,**

**-Model (model name should be unique),**

**-Basic UDI-DI,**

**-Description (return the full name of the device),**

**-EMDN Code,**

**-GMDN Code,**

**-Device Classification and Rules (print: User Input Required)]**

**Image: -**

1. 5 Image Extraction: **-**Extract Image from Input document **‘Refrigeration System Image of “Plasma”,” Blood Bank”, “Chest series”** and **Replace Figure numbers like ‘Figure 1** **Refrigeration System of a Plasma Freezer’ to E.g. ‘Figure x: Refrigeration System of a Plasma Freezer’**. Do not include any references or citations to other sections.

**Text: -**

1. 6 Device Description: **-** The description should contain a statement with the full device name. Followed by what the device does, who uses it and for what purpose. Then mention the environment and conditions where the device is intended to be used. The description should also cover how the device works, including theories surrounding features, variants and operating modes that enable the device to be used for its intended purpose. Do not mention the class or classification of the device. Briefly cover what the System or device components are. If applicable, identify if the device incorporates software/firmware and its role. Conclude the description with details about the presence of medical substance, non-viable animal tissue and non-viable human tissue in the devices. Conclude the section with “The below table provides Device features for [insert Device name].”

**Table: -**

**Device Features of [write a device generic name]:**

**Columns: [-Model :(should be unique),**

**-Temp range (°C),**

**-Capacity (L),**

**-Refrigerant,**

**-Connectivity,**

**-Power cord specifications,**

**-Electrical (voltage, frequency, current),**

**-Product capacity,**

**-Interior dimensions D x W x H (cm),**

**-Exterior dimensions D x W x H (cm),**

**-Shipping weight (kg)]**

**Text: -**

1. 7 Parts delivered with the device**:** Extract all detailed information regarding the parts delivered with the device from the **input document “as-is”.** Provide a list of parts provided with the device.
2. 8 Optional parts delivered with the device**:** Extract detailed information regarding the optional parts delivered with the device and provide a list of optional parts, along with other relevant details provided with the device from the input document “as-is".
3. 9 Operational Conditions**:** Extract all detailed information regarding the operational conditions of the device and provide a list, in bullet points, of environmental conditions the device is designed to operate under. Include factors like indoor/outdoor use, maximum altitude, temperature range, maximum relative humidity, main supply voltage fluctuation limits etc.
4. 10 Factory-Installed Features: **Extract all information** related to the factory installed features of the device as well as the description of the device features in detail, extract it **“exactly as it is given” from the input** **document**. Do not omit or trim any content.
5. 11 Optional features: Extract detailed information regarding the optional features of the device along with the description of the optional features in detail, extract it **“exactly as it is given” from the input** **document**. Do not omit or trim any content.
6. 12 Intended Purpose:Exact description of the intended purpose as described in the device's Instruction for Use (IFU), with exact medical indications (if applicable) and contraindications; claims made in available promotional materials. Intended application of the device, single use/reusable, invasive/non-invasive, implantable, duration of use or contact with the body, maximum number of repeat applications. Extract all the information and print it in a paragraph.
7. 13 Intended patient target groups, Indications, Contraindications and Risks: Print the following “The following data are excerpts from the instructions for use (IFU).”
   * 1. **Intended Patient Target Groups:** Print the following: “There are no specific intended patient target group for [insert device name] as it is intended for [insert intended use of the device].” Then extract the relevant information from the intended patient population or intended patient target group section in the document. The information should be in a paragraph, not bullets.
     2. **Indications:** Extract information regarding indications for use of each of the devices and provide all relevant details like non-intended uses, intended and expected users, non-intended users and other important information like Identification of organs, tissues or body fluids contacted by the device. The information should be in a paragraph, not bullets.
     3. **Contraindications:** Extract the \*\*Contraindications\*\* related to the device from the input document exactly as provided. If there are no contraindications mentioned in the document, look for the ‘not intended for’ statement in the “Intended Use” section of the document and extract that statement without generating any other hallucinated information or making inferences. The information should be in a paragraph, not bullets.
     4. **Warnings and Cautions: Identify and extract each and every WARNING and CAUTION IN THE DOCUMENT. Look for the keyword ‘WARNING’ To identify “WARNING” or understand and identify the warnings based on the context. Look for the keyword ‘CAUTION’ To identify “CAUTION” or understand and identify the cautions based on the context. Ensure that \*\*all warnings and cautions are captured\*\* except for the legend, for example 'WARNING: This symbol indicates potentially hazardous situations which, if not avoided, could result in serious injury or death.' Another example is ‘CAUTION: This symbol, in the context of a CAUTION, indicates a potentially hazardous situation which if not avoided could result in minor to moderate injury or damage to the equipment.’ Do not miss any 'Warning' or 'Caution', they must be extracted fully, even if they are brief or appear in different contexts. Do not extract any content from any other sections.**
     5. **Residual risks/Undesirable effects:** Print the following: “Thermo Fisher Scientific (Asheville) LLC has determined there are no residual clinical risks or undesirable side-effects (e.g., adverse effects, complications) to be conveyed to the patient via the IFU.”
8. 14 Clinical Benefits/Claims: **print** “The intended clinical benefit of the [“Device Name”]to patients as delineated in the marketing documents are summarized with the relevant clinical outcome parameter(s) in [“Table Number”]” Print the following:

**“Clinical Benefit**: Safely maintain blood and blood products at a certain temperature (within acceptable limits) over defined timeframes.)

**Clinical Outcome Parameter**: Ability of the device to accurately maintain temperature (within acceptable limits) over defined timeframes (Performance); Rate of complications/side effects (Safety); Quantity and level of serious incidents (Safety).]”

Then, elaborate on the clinical benefit and clinical outcome parameter provided above using information from the input document file.

1. 15 Relevant General Safety and Performance Requirements: Identify and extract details of compliance to the general safety and performance requirements by the devices.

1. 16 Degree of Novelty of the Device Technology: Print the following: “[Insert Device name] uses well known technology as it is a [insert Generic name of the device] used for [insert intended use of the device] and presents unchanged clinical impact for healthcare. The technology used is based on known technology for [insert intended purpose of the device] with no significant novel features.”
2. 17 Device History: Extract details of Whether the device is already CE marked, whether it is on the market, since when, in what regions, history of the device, including date of past modifications with reasons and description, sales volumes.

**Table: -**

**1. Geographic Commercialization:**

**Columns: [- Country/Market,**

**- Year of First Commercialization,**

**- Sales Volume (find the number of total Seles)]**

**2. Sales per Model:**

**Columns: [- Models (value should be Unique),**

**- Sales (find the number of units sold for model)]**

**Instruction finds the value every model and their sales**

**Text: -**

1. 18 Level of Clinical Evidence Required: **Print the following: “**Thermo Fisher Scientific (Asheville) LLC shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of evidence shall be appropriate in view of the characteristics of [Product Name] and its intended purpose. This Section determines the level of clinical evidence required and Section 4.8.5 will establish if the level of clinical evidence available will meet the level of clinical evidence required.” Specify and justify the level of clinical evidence required for the 'Device Name' to demonstrate conformity with relevant safety and performance requirements. Describe the characteristics and intended purposes of the 'device name', including model specifications and storage conditions. Highlight the training and usage guidelines for User. Explain the rationale for not requiring a PMCF study at this time, referencing the clinical data and post-market surveillance (PMS) activities. Outline the continuous PMS activities and the methods for collecting post-market clinical data. Detail the requirements per MDR Article 61 paragraph 2, including the types of clinical evidence needed to support compliance with GSPR 1 and 8. Discuss the acceptable forms of clinical evidence, including pre-clinical data, post-market surveillance data, clinical investigations, and clinical experience. Provide an alternative approach involving a PMCF plan with user surveys if applicable. Conclude the section with the following: “Alternatively, a PMCF plan including a statistically relevant user survey (e.g. healthcare professional, layperson/patient) as a general method and procedure of PMCF to demonstrate safety and performance of the [insert Generic Name of the device] is considered as an appropriate level of clinical evidence when combined with pre-clinical data on the [insert Generic Name of the device] to harmonized or international standard(s), data from post-market surveillance per MDR Annex III and general methods and procedures of PMCF per Annex XIV Part B.” Insert paragraph breaks as and when required, but do not create separate sections.