1. **Derived Tables:**
   1. Device Legal Manufacturer**:**

**-Manufacturer Name**

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

**-Manufacturer Address**

**-Manufacturing Location**

* 1. Devices Covered by the CER:

**(For each unique model name in Table 2, extract the following fields:)**

**-Device Family Name**

**-Device Family Short Name**

**-Model**

**-Basic UDI-DI**

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

**-EMDN Code**

**-GMDN Code**

**-Device Classification Rule:(find the class of model)**

**-If any field is missing, please print ‘user input required’.**

1. **Image :**

**-**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.

1. **Text:**

Device Description:

Identify and extract a detailed description of the device or devices, in at least 300 words. The section should include a description of the devices, key features, details of the regulatory requirements it meets, expected users of the devices and details about what the characters in the model’s name signify. Conclude the description with details about the presence of medical substance, non-viable animal tissue and non-viable human tissue in the devices.

1. **image**:

Extract given table

1. **Text:**

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.

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".

Operational Conditions**:** Extract all detailed information regarding the operational conditions of the device and provide a list 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.

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.

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.

Intended Purpose:Extract all information regarding the intended purpose of the device and provide details of the intended purposes and uses of each of the devices, separately, included in the document. Include details of the specific models and their intended use for storage, including details on temperatures and product storage durations. Define who should use the device (e.g., professional medical personnel). Mention the conditions under which the device should not be used (e.g., hazardous locations).

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 Population:** Extract all details regarding the devices’ intended patients from the input document**.** If the device is not intended for patients, then mention the intended users.
      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
      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.
      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.
      5. **Residual risks/Undesirable effects:** Identify and extract details of any potential residual clinical risks, undesirable effects or complications that should be conveyed to the patients.

Clinical Benefits/Claims: Identify and extract details of all clinical benefits and claims related to the product.

Device Changes since prior CEP Revision: Extract details of any changes made to the devices since prior CEP revision

Similar Devices: Extract a list of similar devices by common name or device type or look for predicate devices

Equivalent device: Identify and extract details of all equivalent devices of the product