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Questionnaire Guidelines

Consultation of the Medical Device Industry

December 2024

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Context

Medical Device supply chains are complex

The COVID-19 pandemic exposed vulnerabilities in production processes and highlighted the reliance of French Manufacturers on non-European suppliers. With numerous inputs and production stages involved, the industrial vulnerability of the medical device sector is significant, especially due to its reliance on various industries like metallurgy, plastic, electronics and textiles.

Objectives of the Consultation

The purpose of this consultation is to identify and prioritise the vulnerabilities in the manufacturing of medical devices commercialised in France

The Directorate-General for Enterprise (DGE), in partnership with the Directorate-General for Health (DGS), seeks to identify critical areas within manufacturing processes and essential materials to better understand potential risks. Insights from this consultation will help shape public policies to better support the medical device industry.

Each response collected will contribute to the development of policies that are better tailored to address the sector's vulnerabilities.

Target audience

This consultation targets **economic operators manufacturing or commercialising medical devices in France** with CE markings, either under Regulation (EU) 2017/745 or Directive 93/42/EEC for "legacy devices." **Please note that in-vitro diagnostic devices (IVDs) are excluded from this consultation.**

At the start of the questionnaire, you will need to indicate whether:

- **Your company is the legal manufacturer, in which case you'll answer questions related to inputs and manufacturing stages.**

Or

- **Your company is not the legal manufacturer.**

In that case, you can either:

1. **Choose to respond only to questions related to your non-manufacturing activities**. In this case, we encourage you to reach out to your legal manufacturer(s) and share the link to the questionnaire, which they will complete as the manufacturers. An English version of the questionnaire is available on the consultation's dedicated webpage.
2. You may also **choose to answer the questions concerning manufacturing activities on behalf of your legal manufacturer(s).** However, we recommend contacting them to verify the information. If you choose this option, the

questions will be presented as if you were the legal manufacturer of the products.

The time required to input responses for a legal manufacturer or a non-manufacturer responding on behalf of legal manufacturers is estimated at **20–30 minutes for general information** and 10–15 minutes per DM family (EMDN 3-digit family). However, **this estimate does not account for the time needed to gather the necessary information**, which may range from **a few days to several weeks** depending on your organisation's structure.

The estimated response time is 10 minutes in total for a non-manufacturer responding only to questions related to non-manufacturing activities. It is also necessary to review the questions before filling the questionnaire in this case, as some pieces of information have to be gathered.

Reader's Guide

Introduction

Part 0. Identification

Type of Company (according to the company size classification defined in Article 51 of Law No. 2008-776 and Decree No. 2008-1354).

Decree No. 2008-1354 of December 18, 2008, defines the classification of a company for statistical and economic analysis purposes.

- A **start-up/SME** has fewer than 250 employees and an annual turnover of less than €50 million.
- A **mid-sized company** has between 250 and 4,999 employees, and an annual turnover of less than €1.5 billion.
- A **large company** has more than 5,000 employees, and an annual turnover exceeding €1.5 billion.

Part I : Mapping of the medical devices commercialised in France

I-3 to I-5. Number of manufacturing sites.

A manufacturing site is defined, in this case, as a facility with one or more production lines or one or more assembly lines.

I-6. Is the company a subsidiary of a group?

The company may be a subsidiary of either a French or foreign group.

II- products

From this point in the questionnaire, you will be asked to differentiate between each product family of medical devices that you manufacture or distribute.

You will first need to classify your products using the **EMDN classification**. A downloadable list of EMDN codes is available to help you identify your products and their corresponding 3-digit EMDN codes. You can then either type or copy-paste the EMDN code for the relevant product family.

Before starting to fill out the questionnaire for each product family, we recommend preparing a list of the 3-digit EMDN codes that represent the medical device families you produce or market. This will help you avoid duplicates and give you better visibility on the time required to complete the questionnaire.

« Enter your product code »

Please indicate a family of medical devices that your company manufactures or markets in France.

If you manufacture or market multiple medical devices families (according to the 3-digit EMDN classification), you will need to enter each code separately. For each product family, type or copy-paste a single family code, and answer the following questions for the specific family you've indicated.

After completing the questions for this first family, you can specify whether you manufacture or distribute another medical device family. You can then enter a new EMDN code and answer the related questions for that family.

Note:

- **If you manufacture or distribute medical devices corresponding to different 3-digit EMDN codes but with the same inputs and production steps**, you can enter both codes at the same step (e.g., in the "product 1" section), separating them with a comma.
- **If you manufacture or market products across more than six medical device families,** technical limitations prevent us from extending the questionnaire beyond six entries. Therefore, we can provide a second questionnaire for you to complete the questions for additional families without repeating parts I and IV.

  After the sixth product, you will be asked to create a "pseudonym". This can be any word and must remain anonymous. The pseudonym will only be used to link the first questionnaire to the second. On the next page, you will be provided with a new questionnaire link. You can enter the pseudonym you created earlier and continue the questionnaire starting with product 7. Remember to submit the first questionnaire before beginning the second one.

Part II-1: Questions related to the Product Family

II.1.1. to II.1.2. What is your company's market share for this product family?

Please provide a rough estimate of your market share. This information will help us assess the potential impact of identified industrial vulnerabilities on the availability of medical devices for French patients.

II-1.3 to II-1.5. How many competitors with CE marking do you identify for the same product family?

Similarly, this information should be provided as an estimate. It will help us understand the possible effects of industrial vulnerabilities on the availability of medical devices. For competitors within the European Union, combine both French and non-French competitors. For global competitors, include all French, European, and international competitors.

II-1.6. Would you like to add a comment on this first part of the questionnaire?

This free-text zone allows you to provide any additional information you think is relevant (e.g., if this product family targets a specific or niche population).

Part II-2: Industrial vulnerabilities

II-2.1. to II-2.3 Location of each step of the manufacturing process.

Tick the steps that apply to the manufacturing process for the product family in question. In the following step, specify the country where each step takes place when it is outside of the EU. If there are additional steps not listed, please name them and indicate the country where they are performed in the free-text field.

II-2.4 and II-2.5. For each step carried out by subcontractors, where is the subcontracting performed?

As with the previous question, fill in only the steps that are subcontracted. Leave the other steps blank. For the steps that are carried out by subcontractors outside of the EU, please specify the country.

II-2.8. For each product family, identify the essential components and inputs needed for manufacturing, and specify the sourcing type.

List the key components and inputs necessary for manufacturing the medical device, meaning any that, if modified, would constitute a substantial change as defined by regulations. For these critical components, indicate the sourcing type and their use (e.g., medical grade or all-purpose). For the rest of the list, check "non-applicable".

II-2.9. Where applicable, indicate the sourcing origin for each component and input.

For each component involved in the manufacturing process of the product family, tick it and specify the country of origin for the sourcing where relevant.

Part II-3: Identifying situations and causes of supply disruptions

II-3.1. Has your company experienced any recent supply disruptions?

Indicate whether your company has faced supply tensions or disruptions in the past 24 months for the specified categories.

Would you like to provide information about another product?

At this stage, please indicate whether you manufacture or market other families of medical devices in addition to the one you've just provided information for. If you select "yes", you will be redirected to a step where you can enter a new EMDN code.

Part III : CE Marking Under the New EU Regulation (EU 2017/745)

III.1. What is the number of catalog references...

This question applies to all product families of medical devices that you manufacture or market. For each question, indicate the number of catalog references affected, as we are moving beyond the scope of individual medical device families.

Based on your answers, additional questions may appear. For these, you can select one or more responses. Feel free to use the "other" field to provide further details or describe a situation that does not match the given options.

Help and support

Anonymisation of your answers

Your answers should not contain any information that can identify you, and none of the collected responses will be used for identification purposes.

You can save your answers anonymously by creating a pseudonym and password, allowing you to return to the questionnaire at any time.

You may share these access codes within your company to allow multiple team members to contribute to completing the questionnaire. If you use a code to access the questionnaire, no information about the code is stored with your responses. The code is managed separately and will only indicate whether or not you have completed the questionnaire. There is no way to link your access code with your questionnaire responses.

Cookies

Cookies will be used to limit responses to one per IP address.

If you encounter any issues due to the use of cookies, feel free to contact us at dispositif-medical.dge@finances.gouv.fr , and we will provide a solution tailored to your situation (e.g., temporary unblock, using another device, etc.).

Contact us

If you have any questions about the questionnaire, encounter technical difficulties while completing it, or need assistance filling it out, please don't hesitate to contact us by email at: dispositif-medical.dge@finances.gouv.fr .

We encourage you to include your phone number in the email so we can respond promptly.

Please note that the email address and phone number you provide will be used solely to resolve technical issues or address questions related to the questionnaire. They will not be used for any other purpose.

Translation of the questionnaire – consultation of the Medical Devices sector

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Context

This file aims at displaying the questions of the consultation of the medical device industry, that can be reached through *this link*. It is also meant to be used as a translation, as you will notice that the online questionnaire is in French. Please refer to this file for the full translation while answering the questions. You may also write your answers in English. Help and advices on the questions and the expected answers are available in the guide that you can find on the *website of the consultation*.

The questions written in blue may not appear: according to your answers to the previous questions, you may or may not be asked to answer those.

Questions

The questions of this questionnaire vary according to the legal status of your company. Thus, according to your answer to the following question ("choice of the status") you will answer different questions.

Translation of the questionnaire :

First page : context and anonymity

This questionnaire aims at gathering anonymous data from companies in the Medical Devices sector. It will allow for public policies to meet the needs of those industries with more accuracy.

This questionnaire should be answered by any economic operateur manufacturing of distributing CE marked medical devices in France, excluding In-Vitro diagnostic.

For your information :

- You can **save your answers** before submitting the questionnaire with the "finir plus tard" (finish later) option. You'll be asked to create a login. With this login, anyone who needs to have access to the questionnaire can log in and add information. Click on "charger un questionnaire non terminé" and fill in your login and password to be redirected to the answers that were previously saved.
- If you have **technical difficulties** of questions about the questionnaire, you can **reach the team** in charge of the project : dispositive-medical.dge@finances.gouv.fr

0/ Identification

Activity of your company:

- ◉ Legal manufacturer of Medical Devices produced or marketed in France
- ○ Economic operateur related to Medical Devices produced or marketed in France and whose activities are more than those of a legal manufacturer/ are not those of a legal manufacturer.

If you are not a legal manufacturer

As an economic operator not legally manufacturing Medical Devices produced or marketed in France, would you like to:

- ◉ *Respond to questions about your distribution activities and forward this questionnaire to the legal manufacturers of the products you market so they can answer the questions related to manufacturing issues.*
- ○ *Respond to the questions about manufacturing issues yourself by consulting with the legal manufacturers of the products you market.*

If you chose this option, you will be redirected to the questions intended for manufacturers, which you can answer for all the products you market.

If you are the legal manufacturer or decided to answer for the legal manufacturers you work with

I/ Mapping of the medical devices commercialized in France

1.Type d'entreprise (selon la classification des tailles d'entreprise définie dans l'article 51 de la loi n° 2008-776 et le décret n°2008-1354)

- ○ Start-up/SME (fewer than 250 employees, annual turnover less than 50 million euros)
- ○ Mid-size company (250 to 4,999 employees, annual turnover less than 1.5 billion euros)
- ○ Large company (more than 5,000 employees, annual turnover more than 1.5 billion euros)

If you represent the subsidiary of a group : what size is the subsidiary according to the previous classification ? For the following questions, please answer according to the activities of the subsidiary(not the mother group).

2.Number of production sites of the company in France, including overseas departments and territories (excluding headquarters or R&D sites)

- 0
- 1
- Between 2 and 5
- 6 and more

3. If you represent a subsidiary, please write down the category corresponding to your subsidiary.

4.Number of production sites of the company in the European Union, including France (excluding headquarters or R&D sites)

- 0
- 1
- Between 2 and 5
- 6 and more

5.Number of production sites of the company in the world, including France and the EU (excluding headquarters or R&D sites)

- 0
- 1
- Between 2 and 5
- 6 and more

6.Is the company a subsidiary of a group?

- Yes

- ○ No

If yes,

6.1 Location of the group :

- ○ *France*
- ○ *European Union*
- ○ *Outside the EU (please specify)*

II/Product

For this questionnaire, Medical Devices will be classified according to the EMDN classification, as families of devices. For this, the 3 digits EMDN codes will be used. If you happen to manufacture/ distribute several medical devices belonging in the same 3 digits EMDN code, please answer the following questions for all the products (for example, when listing the manufacturing steps of the devices, please select any step that is realized for at least one device in the family associated to this EMDN code)

Reminder : you have to fill out a code with 3 digits, which are one letter followed by two sets of two numbers. For example, if you manufacture/distribute arterial catheters you need to fill out : « C0103 ».

If you manufacture or distribute Medical Devices with different EMDN codes but with the same components and manufacturing steps for a large part of devices in two or more EMDN categories, you may enter both codes, separated by a comma. For example, in this case, please write « A0000,A1111 ». You will then take into account any device belonging to either family when answering the questions.

Please provide the 3-digit EMDN code(s) corresponding to the product families that your company manufactures and/or distributes. If there are several, please start out with one of them. You will be asked later in the questionnaire to address other families.

Using this document, you will find the corresponding EMDN code. Enter only one EMDN code per entry field.

Reminder: The data you need to enter includes 3 digits, which means a letter followed by 4 digits. For example, for arterial catheters, you should enter C0103.

Please indicate the code of the EMDN family *entry field*

How many Medical Devices do you manufacture/distribute in this EMDN category? *entry field*

II-1 - Questions on the product group

II-1.1.

Market share in France for this product category:

- 0%
- > 0 et < 5%
- de 5% à 20%
- de 21% à 50%
- > 50%
- Other :

II-1.2.

Market share in Europe for this product category (estimated share if necessary)

- 0%
- > 0 et < 5%
- From 5% to 20%
- From 21% to 50%
- > 50%
- Other:

II-1.3.

Number of competitors with CE marking identified in the same product category in France

- 0
- 1
- 2
- 3

- 4
- 5
- 6 and more
- Other :

II-1.4

Number of competitors with CE marking identified in the same product category in the European Union (including France)?

- 0
- 1
- 2
- 3
- 4
- 5
- 6 and more
- Other :

II-1.5.

Number of competitors with CE marking identified in the same product category in the world (including the EU)?

- 0
- 1
- 2
- 3
- 4

- ○ 5
- ○ 6 and more
- ○ Other :

II-1.6.
Would you like to provide a comment on this first part of the questionnaire? (e.g. this category of medical devices targets a specific, small population, etc.)

entry field

II-2 - Industrial vulnerabilities in the supply chain

II-2.1.
Select each relevant step of the manufacture of the medical devices, and identify the location in which the steps are carried out.

- ☐ Molding
- ☐ Plastic extrusion
- ☐ Machining of metal materials (turning, milling, etc.)
- ☐ Weaving
- ☐ Casting
- ☐ Filling
- ☐ Sterilisation
- ☐ Assembly
- ☐ Additive manufacturing/3D printing
- ☐ Packaging

For each step selected, a new question will appear to ask you to provide details about the location.

II-2.2

Identify the location where the relevant steps are carried out:

- ☐ Molding
- ☐ Plastic extrusion
- ☐ Machining of metal materials (turning, milling, etc.)
- ☐ Weaving
- ☐ Casting
- ☐ Filling
- ☐ Sterilisation
- ☐ Assembly
- ☐ Additive manufacturing/3D printing
- ☐ Packaging

entry field

II-2.3

If there are one or more additional steps in the manufacture of the medical device, please specify the step and the location where it is carried out.

entry field

II-2.4

Identify the steps carried out by subcontracting, and specify the location where they are carried out.

- ☐ Molding
- ☐ Plastic extrusion
- ☐ Machining of metal materials (turning, milling, etc.)

- ☐ Weaving
- ☐ Casting
- ☐ Filling
- ☐ Sterilisation
- ☐ Assembly
- ☐ Additive manufacturing/3D printing
- ☐ Packaging

II-2.5

For each step subcontracted outside of the EU, specify the main reason :

Reasons :

- Price
- Group policy
- Lack of expertise/ operator in France/ Europe
- Other *entry field*

II-2.6

If there is another reason for which some steps of your manufacturing are carried out as a subcontract outside of the EU ?

entry field

II-2.7

If there are other subcontracted steps in the manufacture of the medical device, please specify the step and the subcontracting location

entry field

II-2.8.

For this family of medical devices, please identify the essential components et identify the sourcing type.

	Not applicable	Direct	Via an intermediary
Medical-grade plastics	○ Not applicable	○ Direct	○ Via an intermediary
Silicone	○ Not applicable	○ Direct	○ Via an intermediary
Electronic components	○ Not applicable	○ Direct	○ Via an intermediary
Semiconductors	○ Not applicable	○ Direct	○ Via an intermediary
Non-woven materials	○ Not applicable	○ Direct	○ Via an intermediary
Textiles	○ Not applicable	○ Direct	○ Via an intermediary
Filters and micro-filters	○ Not applicable	○ Direct	○ Via an intermediary
Aluminium	○ Not applicable	○ Direct	○ Via an intermediary
Titanium	○ Not applicable	○ Direct	○ Via an intermediary
Stainless steel	○ Not applicable	○ Direct	○ Via an intermediary
Rare or precious metals	○ Not applicable	○ Direct	○ Via an intermediary
Other metals or alloys	○ Not applicable	○ Direct	○ Via an intermediary
Ceramics	○ Not applicable	○ Direct	○ Via an intermediary
Cardboard	○ Not applicable	○ Direct	○ Via an intermediary
Wood	○ Not applicable	○ Direct	○ Via an intermediary

II-2.9.

When applicable, please indicate for each component the origin of the sourcing

- ☐ Molding
- ☐ Plastic extrusion
- ☐ Machining of metal materials (turning, milling, etc.)
- ☐ Weaving
- ☐ Casting
- ☐ Filling
- ☐ Sterilisation
- ☐ Assembly
- ☐ Additive manufacturing/3D printing
- ☐ Packaging

II-2.10.

Please specify the use of the components for this family of devices :

	Not applicable	**Medical grade or specific standards**	**All uses**
Medical grade plastics	○ Not applicable	○ Medical grade or specific standards	○ All uses
Silicone	○ Not applicable	○ Medical grade or specific standards	○ All uses
Electronic components	○ Not applicable	○ Medical grade or specific standards	○ All uses

	Not applicable	Medical grade or specific standards	All uses
Semiconductors	○ Not applicable	○ Medical grade or specific standards	○ All uses
Non-woven materials	○ Not applicable	○ Medical grade or specific standards	○ All uses
Textiles	○ Not applicable	○ Medical grade or specific standards	○ All uses
Filters and micro-filters	○ Not applicable	○ Medical grade or specific standards	○ All uses
Aluminium	○ Not applicable	○ Medical grade or specific standards	○ All uses
Titanium	○ Not applicable	○ Medical grade or specific standards	○ All uses
Stainless steel	○ Not applicable	○ Medical grade or specific standards	○ All uses
Rare or precious metals	○ Not applicable	○ Medical grade or specific standards	○ All uses
Other metals or alloys	○ Not applicable	○ Medical grade or specific standards	○ All uses
Ceramics	○ Not applicable	○ Medical grade or specific standards	○ All uses
Cardboard	○ Not applicable	○ Medical grade or specific standards	○ All uses

	Not applicable	Medical grade or specific standards	All uses
Wood	○ Not applicable	○ Medical grade or specific standards	○ All uses

II-2.11

If there are other essential components not listed in the previous table, please provide details on their usage below

entry field

II-3 - Identification of situations and causes of tensions/disruptions

II-3.1

Has your company recently experienced supply tensions or disruptions related to...

	Yes	No
Input/raw material ?	◉ Yes	○ No
Key subcontracting ?	◉ Yes	○ No
finished product ?	◉ Yes	○ No
Other (Regulatory,... ?)	○ Yes	○ No

If you selected « other », please specify

entry field

II-3.1.1.

If you said yes to one or several questions above :

II-3.2

- Describe the solutions that have been implemented if the situation of tension or disruption was due to an internal cause within the company and specify at which step the solution was applied.

II-3.3

- Describe the solutions that have been implemented if the situation of tension or disruption was due to an external cause and specify at which step the solution was applied.

II-3.4

- What were the main causes of these tensions or disruptions

II-3.4.1.

- Internal causes to the company
    - Unavailability of industrial equipment (breakdown, administrative decision, etc)
    - Quality defect
    - Product range rationalisation / commercial strategy
    - Staff or skill deficiency
    - Other

II-3.4.1.1.

If there are other causes to the tensions or disruption, please specify them.

- II-3.4.1.2.
  Do you want to add or specify anything regarding the internal causes of tensions and/ or disruption?

External causes to the company

- Sudden increase in demand (new indication, failure of another manufacturer, etc.) (yes/no)
- II-3.4.2.2 Failure of a subcontractor(yes/no)
- II-3.4.2.3 Failure of a raw material or component supplier (yes/no)
- II-3.4.2.4 Extension of delivery delays (yes/no)
- II-3.4.2.5 other cause (yes/no)

Is your company involved in the manufacturing and/or marketting of other medical devices ?

- Yes
- No

If you check yes :

You'll be sent back to part 1, where you'll be able to provide a new EMDN code and answer about another family of devices.

III/ CE marking under the new regulation (EU 2017/745)

III - 1 - What is the number of your catalog references

a/ That had CE marking under the directive (93/42/CEE) ?

b/Whose CE marking has been transferred under the new regulation (UE 2017/745) ?

c/ those that have recently obtained initial CE marking (under regulation UE 2017/745)

d/ whose CE marking has not yet been transferred under the new regulation, but for which the application has already been made

e/ those that have already have been subject to a market withdrawal due to the implementation of the new regulation (UE) 2017/745

f/ those that could still be subject to a market withdrawal due to the implementation of the new regulation

answer above 0 in E

You indicated that one or more of the medical devices you market or manufacture have already been subject to a market withdrawal due to the implementation of the new Regulation (EU) 2017/745. What is the main reason for this:

- ☐ *Failure of a subcontractor*
- ☐ *Failure of a raw material supplier*
- ☐ *Difficulties of the company in complying with Regulation (EU) 2017/745*
- ☐ *You had a commitment from a notified body that has since withdrawn*
- ☐ *Other, please specify:*

answer above 0 in f

You indicated that one or more of the medical devices you market could still face a market withdrawal due to the implementation of the new Regulation (EU) 2017/745. What is the main reason for this?

- ☐ *Failure of a subcontractor*
- ☐ *Failure of a raw material supplier*
- ☐ *Difficulties of the company in complying with Regulation (EU) 2017/745*
- ☐ *You had a commitment from a notified body that has since withdrawn*
- ☐ *Other, please specify:*

If you are not a legal manufacturer and chose to only answer questions about the activities of your company

I/Mapping of medical devices commercialized in France

1. **Type of company** (according to the classification of company sizes defined in Article 51 of Law No. 2008-776 and Decree No. 2008-1354)

- ○ Start-up/SME (fewer than 250 employees, annual turnover less than 50 million euros)
- ○ Mid-size company (250 to 4,999 employees, annual turnover less than 1.5 billion euros)
- ○ Large company (more than 5,000 employees, annual turnover more than 1.5 billion euros)

2. If you represent the subsidiary of a group : what size is the subsidiary according to the previous classification ? For the following questions, please answer according to the activities of the subsidiary(not the whole groupe).

6. Is the company a subsidiary of a group?

- ○ Yes
- ○ No

6.1 If yes, location of the group :

- ○ *France*

- *European Union*
- *Outside the EU (please specify)*

II/ Group of products

For this questionnaire, Medical devices will be classified according to the EMDN classification, as categories of products. For this, the 3 digits EMDN codes will be used. If you happen to manufacture/ distribute several medical medices belonging in the same 3 digits EMDN code, please answer the following questions for all the products (for example, when listing the manufacturing steps of the devices, please select any step that are realized for at least one device in the EMDN code)

Reminder : you have to fill out a code with 3 digits, which are one letter followed by two sets of two numbers. For example, if you manufacture/distribute arterial catheters you need to fill out : « C0103 ».

If you manufacture or distribute Medical Devices with different EMDN codes but with the same components and manufacturing steps for a large part of the EMDN categories, you may enter both codes, separated by a comma. For example, in this case, please write « A0000,A1111 ».

Question

Please provide the 3-digit EMDN code(s) corresponding to a product family that your company manufactures and/or distributes.

Using this document, you will find the corresponding EMDN code. Enter only one EMDN code per entry field.

Reminder: The data you need to enter includes 3 digits, which means a letter followed by 4 digits. For example, for arterial catheters, you should enter C0103.

Please enter the code for the family

How many Medical Devices do you manufacture/distribute in this EMDN category?

II-1 - Questions about product category and product

II-1.1.
Market share in France for this product category

- 0%
- Between 0% and 5%
- 5% to 20%

- 21% to 50%
- > 50%
- Other :

II-1.2.
Market share in Europe for this product category (estimated share if necessary)

- 0%
- > 0 et < 5%
- de 5% à 20%
- de 21% à 50%
- > 50%
- Other

II-1.3.
Number of competitors with CE marking identified in the same product category in France

- 0
- 1
- 2
- 3
- 4
- 5
- 6 and more
- Other :

II-1.4.

Number of competitors with CE marking identified in the same product category in the European Union (including France)?

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6 and more
- ○ Others :

II-1.5.

Number of competitors with CE marking identified in the same product category in the the world (including European Union)

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6 and more
- ○ Others :

II-1.6

Would you like to provide a comment on this first part of the questionnaire? (e.g. this category of medical devices targets a specific, small population, etc.)

II-3.1.

Has your company recently experienced supply tensions or disruptions related to…

	Yes	**No**
Logistics and transportation	◉ Yes	○ No
Key subcontracting ?	◉ Yes	○ No
finished product ?	◉ Yes	○ No
Other (Regulatory,… ?)	○ Yes	○ No

II-3.1.1

If you selected « other », please specify

If you said yes to one or several questions above :

- II-3.2. Describe the solutions that have been implemented if the situation of tension or disruption was due to an internal cause within the company and specify at which step the solution was applied.
- II-3.3. Describe the solutions that have been implemented if the situation of tension or disruption was due to an external cause and specify at which step the solution was applied.
- II-3.4. What were the main causes of these tensions or disruptions
    - II-3.4.1.Internal causes to the company
        - Unavailability of industrial equipment (breakdown, administrative decision, etc)
        - Quality defect
        - Product range rationalisation / commercial strategy
        - Staff or skill deficiency
        - Other

- II-3.4.1.1. If other please specify
- II-3.4.1.2. Are there more details that you would like to share about internal causes of tension and/or disruption?
- II-3.4.2.1. External causes to the company
    - Sudden increase in demand (new indication, failure of another manufacturer, etc.) (yes/no)
    - Failure of a manufacturer (yes/no)
    - Extension of delivery delays (yes/no)
    - other cause (spécify)

Is your company involved in the manufacturing and/or marketting of other medical devices ?

- Yes
- No

If you check yes

You'll be sent back to part 1. You will be able to indicate another EMDN code and answer the questions for this new family of devices.

III/ CE marking under the new regulation (EU 2017/745)

III.1.

What is the number of your catalog references…

a/ That had CE marking under the directive (93/42/CEE) ?

b/ Whose CE marking has been transferred under the new regulation (UE 2017/745) ?

c/ Those that have recently obtained initial CE marking (under regulation UE 2017/745)

d/ Whose CE marking has not yet been transferred under the new regulation, but for which the application has already been made

e/ Those that have already have been subject to a market withdrawal due to the implementation of the new regulation (UE) 2017/745

f/ Those that could still be subject to a market withdrawal due to the implementation of the new regulation

answer above 0 in E

III.1.1.

You indicated that one or more of the medical devices you market or manufacture have already been subject to a market withdrawal due to the implementation of the new Regulation (EU) 2017/745. What is the main reason for this:

- ☐ *Failure of a subcontractor*
- ☐ *Failure of a raw material supplier*
- ☐ *Difficulties of the company in complying with Regulation (EU) 2017/745*
- ☐ *You had a commitment from a notified body that has since withdrawn*
- ☐ *Other, please specify:*

answer above 0 in f

III.1.2.

You indicated that one or more of the medical devices you market could still face a market withdrawal due to the implementation of the new Regulation (EU) 2017/745. What is the main reason for this?

- ☐ *Failure of a subcontractor*
- ☐ *Failure of a raw material supplier*
- ☐ *Difficulties of the company in complying with Regulation (EU) 2017/745*
- ☐ *You had a commitment from a notified body that has since withdrawn*
- ☐ *Other, please specify:*