University of Technology of Compiègne

ECONOMIC OPERATORS STATUS MANAGEMENT

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by :

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Glossary

AL	Air Liquide
ALH	Air Liquide Healthcare
ALMS	Air Liquide Medical Systems
AR	Authorized Representative
CA	Competent Authority
EEA	European Economic Area
EO	Economic Operator
MD	Medical Device
MDR	Medical Device Regulation 2017/745
NB	Notified Body
QA	Quality Agreement

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Abstract

The healthcare industry is highly monitored due to the potential risk that may occur if the medical devices are not manufactured in compliance with the applicable regulations and standards. Thus, in order to guarantee the security of the patients/users, several regulations are set that allows a better management of this industry, such as the regulation 2017/745 of the European Council on medical devices (MDR) published in April the 5th 2017, amending the previous directive 92/42/CEE.

The new regulation on medical devices will come into effect in May 2020. Once activated the requirements become mandatory obligations for manufacturers, authorized representatives, importers, distributors and any other entity or actor related to this field of industry. Therefore, a better understanding of the MDR would be effective for an efficient application of its requirements.

In this context, the present dissertation introduces a fully analysis of the four economic operators articles in the MDR, in order to identify the gap analysis between the current and the new obligations. Along with highlighting the major impacts of the requirements of the MDR in the case of ALMS on several aspects, such as the clauses of the quality agreements between the different actors, as long as the supply chain management of the distributors.

Résumé

L'industrie des dispositifs médicaux fait l'objet d'une surveillance étroite en raison du risque potentiel qui pourrait survenir lors de l'utilisation des dispositifs médicaux, d'où la nécessité de les fabriquer conformément aux réglementations et aux normes en vigueur. Par conséquent, afin de garantir la sécurité du patient/utilisateur, la réglementation a beaucoup évolué. En 2017 le secteur des dispositifs médicaux a accueilli le nouveau règlement Européen 2017/745, remplaçant la directive européenne 93/42/CEE.

Le Règlement 2017/745 du 5 avril 2017 relatif aux dispositifs médicaux s'appliquera en Mai 2020.Ainsi, ces exigences deviendront des obligations pour les fabricants ainsi que pour toutes entités et acteurs liés au secteur des dispositifs médicaux. De ce fait, une meilleurecompréhension des articles du MDR permettra une application plus efficace de ces exigences.

Dans ce contexte, le présent rapport introduit une analyse complète des articles réglementaires liées aux quatre opérateurs économiques (Fabricant, Mandataire, Importateur, Distributeur) afin d'identifier l'écart entre l'existant et les nouvelles obligations. Le rapport présente également les impacts majeurs du règlement 2017/745 sur ALMS, tels que la mise à jour des contrats entre les différentsopérateurs économiques ainsi que la gestion des distributeurs vis-à-vis des exigences du règlement.

Introduction

In the last few decades, the population has rapidly increased, this increase has created more need to healthcare services and instruments. As a result, the number and size of medical devices industry increased as well. Yet, in order to guarantee the safety of the patient, this type of industry became highly monitored. Therefore, the regulation related to medical devices has evaluated a lot. In 2017, the European Parliament and Council had published the 2017/745 regulation on medical devices that amends the previous 93/42/CEE directive.

Due to the new regulatory context, several changes and updates has been set. Among the main new requirements of the regulation is the reinforcement of the economic operators' roles and responsibilities especially for the distributors.

Air Liquide Medical Systems is a sub-branch of the group Air Liquide, devoted to the medical devices industry, the main mission of ALMS is the manufacturing of different medical devices, but it is also a distributor, an importer and an authorized representative of other manufacturers. Hence, it must be compliant with the requirements of the regulations for each of the four economic operators' status, by meeting all the regulatory obligations.

I joined the Regulatory Affairs and Quality department at Air Liquide Medical Systems in February 18th as a trainee in the Homologation service, for the purpose of analyzing the 2017/745 regulation on medical devices for the four economic operators, in order to identify the gap analysis and work on the main impacts, changes and updates based on that analysis.

This dissertation highlights the major impacts of the regulation on the economic operators, especially for the distributors. By focusing on the remedial actions to perform in order to comply with the new requirements, such as the changes on the quality agreements between the different actors, as well as the supply chain management of the distributors, etc...

The organization of this dissertation is as follows. The first chapter presents the context of the project/internship, the issue to solve and the objectives. The second chapter introduces the methodologies and the actions taken in order to solve the issue in question. Finally, the third chapter is about the project results and the impacts, then presenting the internship personal impact and the conclusion.

Chapter I

Context, Issue and Objectives

1. Introduction of the host facility : Air Liquide Medical Systems France

1.1. The group Air Liquide :

The group Air Liquide was created in 1902, currently it is a world leader in medical gases, and it is present in over 80 countries with over 3 million customers and patients [1]. The group is involved in a wide variety of industries, from steelmaking, energy, chemistry and automobile manufacturing to aviation, food processing, pharmaceuticals, space and electronics [3]. Figure 1 describes the major fields of the group.

The Healthcare field (medical devices, medical gases...) of the group where Air Liquide Medical Systems belongs, is considered as a key partner of the healthcare professionals in France[3]. The group's Healthcare business line represents 17% of the revenue figure of the group [2]. The main goal of the healthcare branch is to help optimizing the patient care across the treatment spectrum.

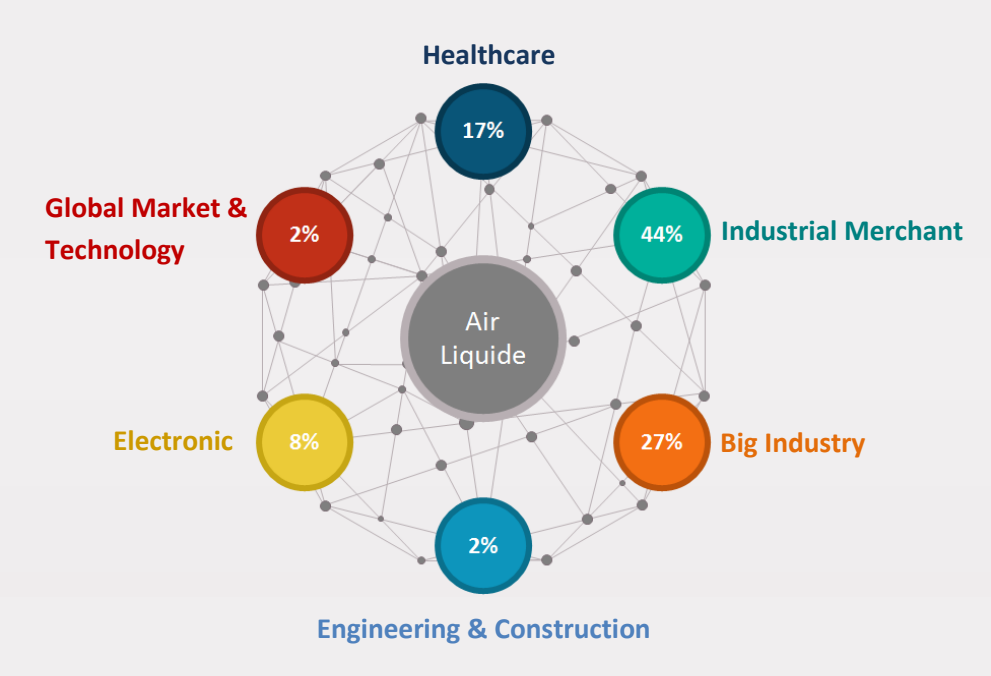


Figure 1. Air Liquide economic fields [2]

1.2. The branch Air Liquide Medical Systems (ALMS)

Air Liquide Medical Systems is a subsidiary company devoted to medical devices of the branch Air Liquide Healthcare of the group. The main function of ALMS is the manufacturing of medical ventilators, as well as different medical devices related to the medical gases supply. However, beside the role of a manufacturer, Air Liquide Medical Systems performs also the role of an importer, a distributor and an authorized representative for the related medical devices (respiratory masks, medical devices' accessories...) that are not manufactured by the company itself.

Figure 2. Medical Devices of ALMS

1.3. The Regulatory Affairs and Quality department at ALMS

The Regulatory Affairs and Quality department is divided into two divisions, the Regulatory Affairs (RA) service and the Quality service. The synergy between both divisions allows to guarantee the compliance of the medical devices of the company to the applicable related regulations and standards. Along with maintaining the licences and certificates updated in the different geographical areas, the department also insure the communication with the notified bodies as well as the competent authorities.

The Regulatory Affairs and Quality service is connected to all the other departments of the company (R&D, Marketing, Sales...). Therefore, this department have a key role in the company, since it is responsible for placing the products manufactured onto the market.

2. Regulatory context and general definitions

2.1. The European Regulation 2017/745 on Medical Devices

The goal of the medical devices' regulations in Europe is to insure that only the devices meeting the necessary requirements of security and performance are put on the European market. The purpose is guaranteeing the patient security as well as the security of any other user of the devices.

The European regulation of April the 5th 2017 on medical devices is an obligatory legal act to all the member states of the European Union. It is directly applicable in its legal order starting from May 26th of 2020. This regulation will harmonize the European legal regime regarding the medical devices, by amending the previous medical devices directive 93/42/CEE. Among the major changes brought by the MDR :

- ✓ The traceability (Eudamed System)
- ✓ The roles and responsibilities of the economic operators (much reinforced)
- ✓ The vigilance
- ✓ The medical devices' criteria of classification (more strict)
- ✓ The medical devices' field (much larger)

2.2. General definitions

- **Medical Device**

The Medical device is defined according to the Regulation 2017/745 [4] as "*any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes :*

- ✓ *Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease*
- ✓ *Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability*
- ✓ *Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- ✓ *Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations*

And which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means." [4].

- **Economic operator**

The Economic Operator is defined according to the Regulation 2017/745 [4] as "a *manufacturer, an authorized representative, an importer, a distributor*" [4]

- **Manufacturer**

The Manufacturer is defined according to the Regulation 2017/745 [4] as "*a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark*" [4].

- **Authorized Representative**

The Authorized Representative is defined according to the Regulation 2017/745 [4] as "a*ny natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation*" [4].

- **Importer**

The Importer is defined according to the Regulation 2017/745 [4] as "*any natural or legal person established within the Union that places a device from a third country on the Union market*" [4].

- **Distributor**

The Distributor is defined according to the Regulation 2017/745 [4] as "*any natural or legal person in the supply chain, other than the manufacturer or the importer that makes a device available on the market, up until the point of putting into service*" [4].

3. The issue to solve

The homologation process including the CE marking at Air Liquid Medical System is a very complicated process due to the massive data to be handled (over 120 countries of sales for different categories of Medical Devices), and because it's linked to different departments (R&D, Sales, Marketing…), beside that it requires contacting different entities (Distributors, Importers…). These difficulties led to a convoluted process. Moreover, the European regulation 2017/745 will definitely have an impact on the regulatory affairs process that may led to a much heavier managing.

In this context, the issue to solve during this internship of six months is to determine the impact of the European regulation 2017/745 on the CE marking process at ALMS. Along with conducting the major obligations and updates related to the regulation. Moreover, notifying the related economic operators (distributors, importers, authorized representatives) of the regulation's impact and the taken actions.

4. Perceptible objectives of the missions

The objectives of this internship missions are reveled in the following four actions:

4.1. The Gap Analysis of the MDR new requirements related to the Economic Operators

The objective is to identify the gap analysis of the MDR's new requirements for each of the four Economic Operators (manufacturers, authorized representatives, importers, distributors), in order to proceed with the identification of the major impacts of the MDR's new obligations for the company.

4.2. The Quality Agreement for the EEA distributors

The objective regarding the quality agreement is to determine the necessary changes related to the new requirements of the MDR.

4.3. The distributors supply chain management inside the EEA

The distributor supply chain management inside the EEA, is about creating a cartography of the distributors per device that allows a better view of the fleet of distributors in each country of the EEA and for each medical device manufactured by ALMS.

4.4. The distributors supply chain management worldwide

In addition with checking the EEA distributors, the second related objective is to identify ALMS' authorized medical devices distributed in the different countries of sales worldwide, by gathering all the data and information related to the distributors/products for a further implementation in the company's database in order to improve the supply chain management of the ALMS' distributors worldwide.

Chapter II

Adopted Methodologies

1. Introduction to the adopted methodologies and followed steps

The methodologies adopted for solving the issue, and for meeting the internship objectives, consist at first, of determining the regulation 2017/745 articles related to the Economic Operators, in order to proceed with a profound analysis of those articles. Once the analysis is done, the major updates and obligations are set, to implement the necessary changes in order to comply with the new obligations of the regulation. Therefore, the Quality Agreement and the supply chain management of the distributors, were updated in order to meet with the MDR's requirements.

2. Regulation 2017/745 : the analysis of the Economic Operators' articles

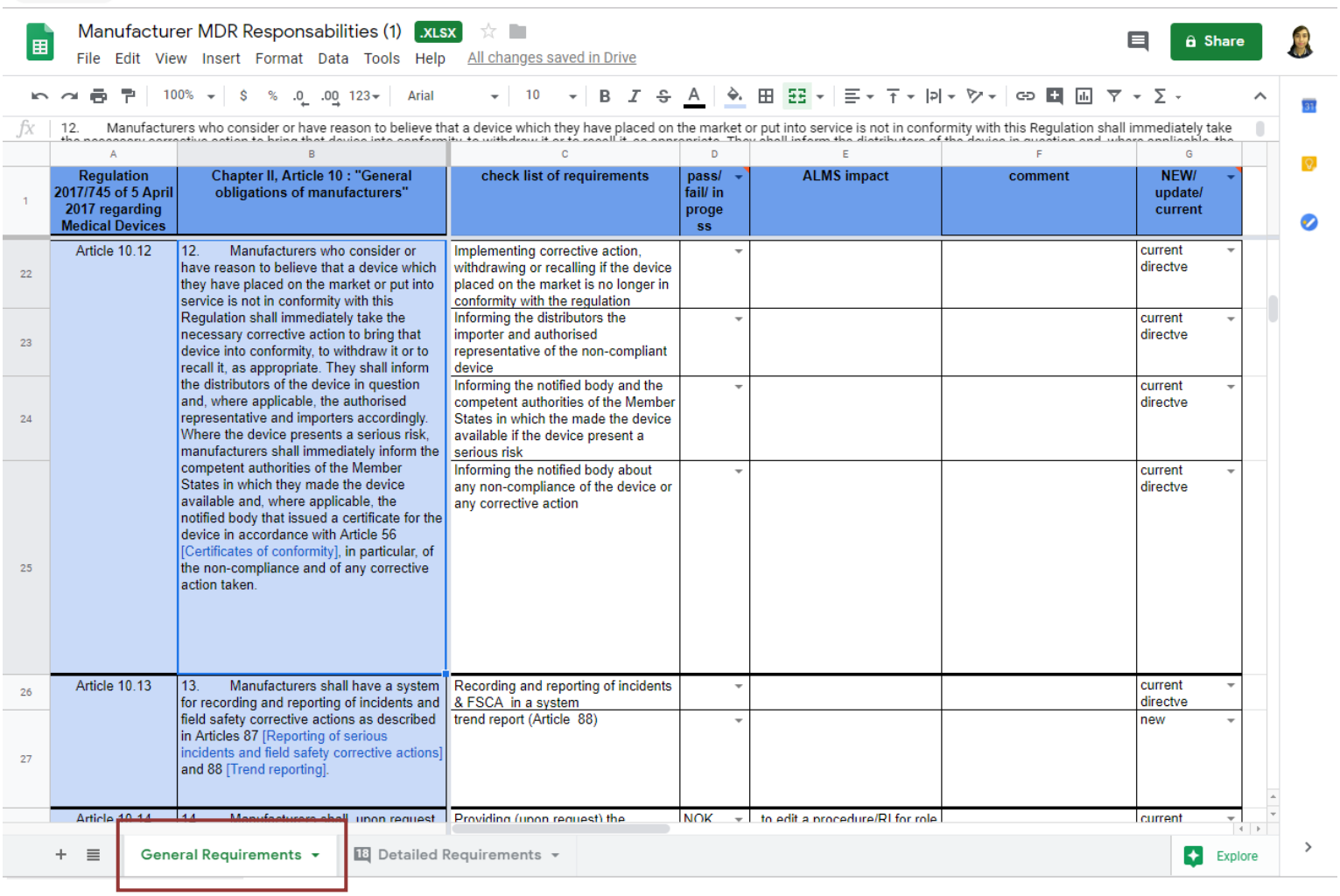
The analysis covers the economic operators' regulatory articles, which are set in the second chapter of the regulation 2017/745, more precisely from article 10 to 14. However, all the regulation was explored in order to identify all the further requirements and obligations related to the four economic operators in the rest of the regulation. As a result, the analyzed articles are set as shown in table 1 below.

Manufacturer	Authorized Representative	Importer	Distributor
Article 10.1 to10.16 Article 25.2	Article 11.1 to11.7 Article 12 Article 25.2	Article 13.1 to 13.10 Article 16.1 to16.4 Article 25.1 Article 25.2 Article 30.3	Article 14.1 to14.6 Article 16.1 to16.4 Article 25.1 Article 25.2

Table 1. The Economic Operators treated Articles [Source Author]

The Regulation 2017/745 analysis consists of creating four checklists, one for each economic operator. Those checklists are created in Google Sheets files (as described in figures 3 and 4) so that they can be shared with the concerned actors. Each file contains two sheets, the first one presents the general requirements of the economic operator without getting into the details of each requirement, and the second sheet presents a further analysis of the obligations according to the exact article of each obligation in the regulation. Figures 3 and 4 below describe the General and the Detailed Requirement Sheets of the checklist (respectively) in the case of the Manufacturer (emptied from the confidential data). Moreover, the four checklists focus on the following criteria:

- ✓ Presenting the regulatory subparagraphs of each article in the main chapter (Figure 3 : Column A and B)
- ✓ To interpret the regulatory subparagraph, by appointing all and every requirement in order to manage it separately as a checklist requirement (Figure 3 : Column C).
- ✓ Checking if the company already manages the requirement or if it is not managed at all, or managed partially but needs an update (Figure 3 : Column D).
- ✓ In case of a requirements that it is not already of partially managed. Indicating the impact on ALMS: the procedures to create or to update, the concerned actors… in order to comply with the new requirement or the update (Figure 3 : Column E and F).
- ✓ Checking whether the requirement pointed out is a new obligation, or already covered by the directive 93/42/CEE, or an update (Figure 3 : Column G).



	A	B	C	D	E	F	G
1	Regulation 2017/745 of 5 April 2017 regarding Medical Devices	Chapter II, Article 10 : "General obligations of manufacturers"	check list of requirements	pass/ fail/ in progess	ALMS impact	comment	NEW/ update/ current
22	Article 10.12	12. Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly. Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56 [Certificates of conformity], in particular, of the non-compliance and of any corrective action taken.	Implementing corrective action, withdrawing or recalling if the device placed on the market is no longer in conformity with the regulation				current directve
23			Informing the distributors the importer and authorised representative of the non-compliant device				current directve
24			Informing the notified body and the competent authorities of the Member States in which the made the device available if the device present a serious risk				current directve
25			Informing the notified body about any non-compliance of the device or any corrective action				current directve
26	Article 10.13	13. Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 [Reporting of serious incidents and field safety corrective actions] and 88 [Trend reporting].	Recording and reporting of incidents & FSCA in a system				current directve
27			trend report (Article 88)				new
	Article 10.14	14. Manufacturers shall upon request	Providing (upon request) the	NOK	to edit a procedure/RI for role		current

Figure 3. The General Requirements sheet of the Manufacturer checklist [Source Author]

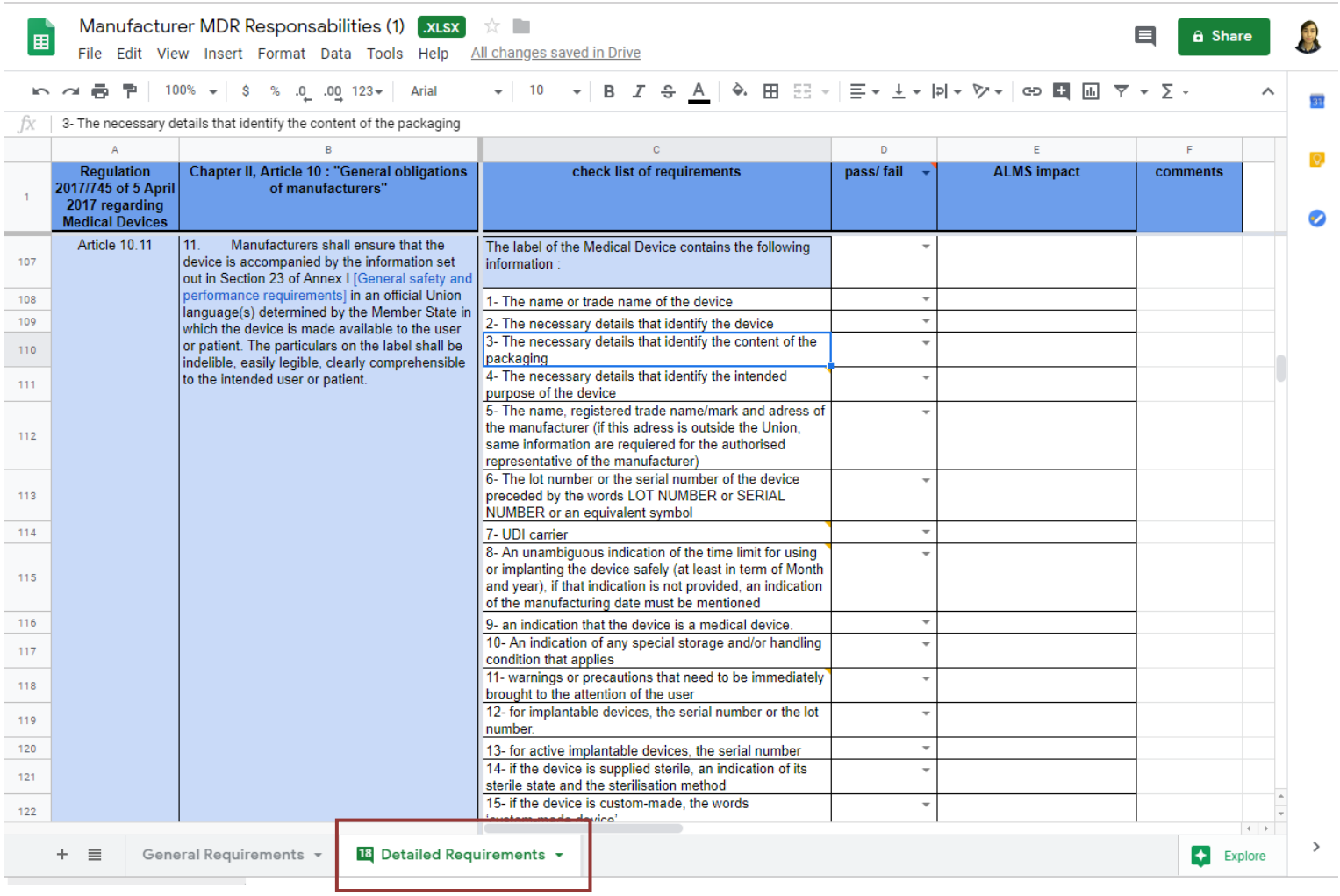


Figure 4. The Detailed Requirements sheet of the Manufacturer checklist [Source Author]

3. The Quality Agreement update for the EEA distributors

A Quality Agreement between the company and its distributors is a document that defines both specific regulatory and quality requirements for the medical devices distribution aspect, as well as defining which party is responsible for the execution of those duties.

The MDR conducted analysis allowed to identify the requirements relate to the Economic Operators, as a result, the template of the quality agreement between ALMS and its distributors must be updated in order to include the new requirements of the regulation

2017/745. The further objective of this change is to dispatch the updated quality agreement to the different distributors of the EEA for its implementation.

4. The supply chain management of the distributors

4.1. The distributors supply chain management inside the EEA

The first method consist of gathering information about the European distributors first, for each medical device manufactured by the company. To do so, a cartography was created in Google Sheets containing several sheets in order to be shared with all the sales representatives of ALMS in the different countries of sales inside the EEA. Thus, asking them to complete the sheet carrying their names by indicating the legal name of the distributors to whom they sale the medical devices in the countries of sales covered by them. By gathering this information, we could generate the cartography of the distributors that allows a larger view of the medical devices distribution status in Europe. Appendix E describes the aforementioned cartography of the distributors.

4.2. The distributors supply chain management worldwide

Managing the worldwide distributors of ALMS in the countries of sales is a challenging task due to the high number of both distributors and countries. Therefore, the second method for the supply chain management of the distributors consist of dealing with the worldwide distributors by providing them a list containing all the medical devices already sold in their countries of distribution, and asking them to validate or not the current authorization status of the medical device distributed by them.

Chapter III

Results and Impacts

1. The analysis' main results :

1.1. Obligations of Manufacturers

The MDR obligations for manufacturers are listed in Appendix A. Yet, the main new and updated requirements are the following :

- ✓ Conducting the registrations of the Manufacturer and the Medical Device in Eudamed.
- ✓ Providing free samples of the medical device to the competent authorities at their request, and if it is not possible, providing access to the device.
- ✓ Including the post market surveillance and the trend reporting in the technical documentation of the medical device.
- ✓ Conducting the registration in Eudamed of any sub-contractor performing changes in the manufacturing or the design of the Medical Device.
- ✓ The Manufacturers must Identify to the competent authority for at least 10 years since the device has been placed on the market : any economic operator to whom they have directly supplied a device, any economic operator who has directly supplied them with a device and any health institution or healthcare professional to which they have directly supplied a device.

1.2. Obligations of the Authorized Representatives

The MDR obligations for the Authorized Representative are listed in Appendix B. Yet, the major new and updated requirements are the following :

- ✓ The legally liability of the Authorized Representative for a defective device on the same basis as the manufacturer.
- ✓ Informing the competent authority (and where applicable the notified body) when ending the mandate and mentioning the reasons of the cloture.
- ✓ The Authorized Representatives must identify to the competent authority for at least 10 years since the device has been placed on the market : any economic operator to whom they have directly supplied a device, any economic operator who has directly supplied them with a device and any health institution or healthcare professional to which they have directly supplied a device.
- ✓ Conducting the economic operator registration of the Authorized Representative in Eudamed.
- ✓ The Authorized Representative must verify that the device is having an UDI.

1.3. Obligations of the importers

The MDR obligations for Importers are listed in Appendix C. Yet, the major new and updated requirements are the following:

- ✓ The Importer must indicate his contact details on the device or on its packaging or in a document accompanying the device, and ensure that any additional label does not obscure any information on the label provided by the manufacturer.
- ✓ The importer must perform the Economic Operator registration in Eudamed.
- ✓ The Importer must verify that the device is having an UDI.
- ✓ The Importer must ensure that the storage and the transport conditions comply with the conditions set by the manufacturer.
- ✓ The Importer must Keep a register of complaints, recalls and withdrawals of the non-conforming devices (Already required by the ISO 13485:2016)
- ✓ The Importer must co-operate with the manufacturer, the manufacturer's authorized representative and the competent authorities to ensure that the necessary corrective actions/withdraws/recalls are performed correctly.
- ✓ The Importer must provide free samples of the device to the competent authorities at their request, and if it is not possible, providing them access to the device.
- ✓ The Importers must identify to the competent authority for at least 10 years since the device has been placed on the market : any economic operator to whom they have directly supplied a device, any economic operator who has directly supplied them with a device and any health institution or healthcare professional to which they have directly supplied a device.

1.4. Obligations of the distributors

The MDR obligations for Distributors are listed in Appendix D. Yet, the major new and updated requirements are the following:

- ✓ The Distributor must verify that the device is having an UDI.
- ✓ The Distributor must ensure that the storage and the transport conditions comply with the conditions set by the manufacturer.
- ✓ The Distributor must co-operate with the manufacturer, the manufacturer's authorized representative and the competent authorities to ensure that the necessary corrective actions/withdraws/recalls are correctly performed.
- ✓ The Distributor must provide free samples of the device to the competent authorities at their request, and if this is not possible, providing access to the device.
- ✓ The Distributors must identify to the competent authority for at least 10 years since the device has been placed on the market : any economic operator to whom they have directly supplied a device, any economic operator who has directly supplied them with a device and any health institution or healthcare professional to which they have directly supplied a device.

2. The Impact of the regulation analysis on ALMS

2.1. The gap analysis of the EO related requirement on ALMS

The gap analysis of the regulation 2017/745 allows to identify whether the regulatory requirements are being met and, if not, what steps should be taken to ensure they are met successfully for ALMS.

After the conduct of the MDR gap analysis, several actions has been identified to get ALMS in compliance with the new requirements of the MDR economic operators' articles. However, for the time being the major conducted actions are the quality agreement updating as well as the distributors management inside the EEA.

2.2. The impact on the Quality Agreement between ALMS and its distributors inside EEA

As a pursuit to the taken actions of the regulatory impact on the distributors. The current Quality Agreement between the company and its distributors must be updated for the EEA distributors in order to include the new clauses related to the new requirements of the regulation 2017/745, such as:

- ✓ The Manufacturer assigns an UDI to the Medical Device and performs all the necessary registration of the Medical Device in the European database on Medical Devices Eudamed.

- ✓ If the Medical Device is imported, the Distributor must ensure that the Importers has indicated on the device or on its packaging or in a document accompanying it, their name, registered trade name or registered trademark, their registered place of business and the address at which they can be contacted.

- ✓ Distributors must ensure that the Manufacturer assigns an UDI to the Medical Device and performs all the necessary registration of the device in the European database Eudamed.

- ✓ Upon request, the Distributor undertakes to provide free samples of the Medical Device to the competent authority, where that is impracticable, grant them access to the Medical Device.

2.3. The Cartography of the European Distributors

The cartography of the distributors conducted allowed a larger and simplified vision of the distributors inside the EEA, by indicating their legal distributor's name for each medical devise manufactured by ALMS France, and for each country of sales (as shown in Appendix E). The cartography will be implemented in the company's documentary database as a document reflecting the current distribution details of the medical devices in Europe.

2.4. The impact on the distribution worldwide

In order to insure that the medical devices marketed and distributed by ALMS are only sold and dispatched in the approved geographies, the direction decided to create a "positive list of countries" (Countries where the Medical Device is currently authorized), this list will reflect the current authorization status of the devices in the country in question. Therefore, in order to meet this project, I have been contacting the distributors of ALMS in the different countries of sales, asking them to validate (or not) the Medical Devices references distributed by them.

After receiving the results from the distributors in the countries of sales worldwide (outside the EEA). The data are gathered in the same file so that it can be uploaded easily in the company's database. Then the countries is considered as covered, so a follow up sheet (figure 5) is completed as "Done" for it.

PROJECT STATUS

File Edit View Insert Format Data Tools Add-ons Help All changes saved in Drive

Share

	A	B	C	D	E	F	G
1	Area	Countries	MDs' list for distributors	MDs' List Status	Comments	Answered => integrated in Sage table	
2	NAEMEA	Algeria	Done	List sent	Oxymed & Fluidal & Impomed	Yes	
3	NAEMEA	Angola	No Need	Sales not allowed			
4	LATAM	Argentina	Done	List sent			
5	SEA	Australia	Done	List sent			
6	NAEMEA	Benin					
7	NAEMEA	Botswana					
8	LATAM	Brazil	Done	List sent			
9	SEA	Brunei					
10	NAEMEA	Burkina Faso					
11	SEA	Cambodia					
12	NAEMEA	Cameroon					
13	NAEMEA	Canada	No Need	Already handled			
14	NAEMEA	Central African Republic					
15	NAEMEA	Chad					
16	LATAM	Chile	Done	List sent			
17	SEA	China					
18	LATAM	Colombia	Done	List sent			
19	NAEMEA	Comoros					
20	NAEMEA	Congo	No Need	Sales not allowed			
21	LATAM	Costa Rica	Done	List sent			
22	NAEMEA	Djibouti					
23	LATAM	Dominican Republic	Done	List sent			
24	LATAM	Ecuador	Done	List sent			
25	NAEMEA	Egypt	Done				
26	NAEMEA	Gabon					
27	NAEMEA	Ghana					
28	NAEMEA	Guinea					
29	SEA	Hong Kong					
30	SEA	India	Done				
31	SEA	Indonesia	Done	List sent			

MD List Sent/not sent | Sheet2 | Explore

Figure 5. Checklist for the status of the Worldwide Distributors project [Source Author]

Personal internship impact

This internship allowed me to have a closest look on the different roles and responsibilities of the four economic operators by exploring the MDR and its obligations, along with applying it on a fully medical devices industrial facility such as ALMS. In fact, my experience at ALMS allowed me to gain several business skills related to the regulatory affairs, and it made me reinforce the academic skills that I already gained regarding this field of industry.

Conclusion

The regulation 2017/745 on medical devices introduces several new requirements regarding the obligations of the four economic operators. A better understanding in advance of these requirements would be effective for an efficient application of the MDR. Therefore, the regulation's analysis conducted in this internship helps identifying the regulatory requirements of the EO, in order to well frame their roles and responsibilities.

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Appendix A

Article 10 : General obligations of manufacturers

Regulation 2017/745 on Medical Devices	Chapter II, Article 10 : "General obligations of manufacturers"	check list of requirements	OK / NOT OK
Article 10.2	2. Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I[General safety and performance requirements].	Risk management system (Annex I)	
Article 10.3	3. Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 [Clinical evaluation]and Annex XIV [Clinical evaluation and post-market clinical follow-up], including a PMCF.	Clinical evaluation (article 61)	
		Post-market clinical follow-up (annex XIV)	
Article 10.4	4. Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II [Technical documentation] and III [Technical documentation on post-market surveillance]. The Commission is empowered to adopt delegated acts in accordance with Article 115 [Exercise of the delegation] amending, in the light of technical progress, the Annexes II [Technical documentation] and III [Technical documentation on post-market surveillance].	Technical documentation (annex II and III)	
Article 10.6	6. Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 19 [EU declaration of conformity], and affix the CE marking of conformity in accordance with Article 20 [CE marking of conformity].	EU declaration of conformity with UDI-DI (article 19)	
		CE marking in IFU, label (article 20)	
Article 10.7	7. Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 [Unique Device Identification system] and with the registration obligations referred to in Articles 29 [Registration of devices in EUDAMED] and 31 [Registration of manufacturers, authorised representatives and importers in EUDAMED].	Unique Device Identification system (article 27 &annex VI)	
		The registration of the device in Eudamed (Article 29) + registration of manufacturer in eudamed (article 31)	

Article 10.8	8. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56 [Certificates of conformity], available for the competent authorities for a period of at least ten years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market. Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof. A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3) [Authorised representative], ensure that the authorised representative has the necessary documentation permanently available.	Technical documentation is kept at least 10 years (after placing of the device in the market)	
		The EU declaration of conformity is kept at least 10 years (after placing of the device in the market)	
		Copies of any relevant certificate such as amendment, supplements..., (See Article 56 = certificates of conformity) are kept at least 10 years (after placing of the device in the market)	
Article 10.9	9. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.The quality management system shall address at least the following aspects:	The production is in conformity with the regulation	
		Changes in device design or characteristics are taken into account	
		Changes in the harmonized standards are taken into account	
		Changes in the Common specifications (Article 9) are taken into account	
		Quality management system (section 9 article 10)	
Article 10.10	10. Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 83 [Post-market surveillance system of the manufacturer].	Post-market surveillance system (Article 83)	
Article 10.11	11. Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I [General safety and performance requirements] in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible, clearly comprehensible to the intended user or patient.	The device is accompanied by the required information (Section 3 Annex I)	
		The devices information are in the official Union language(s) determined by the Member State in which the device is made available	
		The label is indelible, easily legible and clearly comprehensible	

Article 10.12	12. Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly. Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56 [Certificates of conformity], in particular, of the non-compliance and of any corrective action taken.	Implementing corrective action, withdrawing or recalling if the device placed on the market is no longer in conformity with the regulation	
		Informing the distributors the importer and authorized representative of the non-compliant device	
		Informing the notified body and the competent authorities of the Member States in which the made the device available if the device present a serious risk	
		Informing the notified body about any non-compliance of the device or any corrective action	
Article 10.13	13. Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 [Reporting of serious incidents and field safety corrective actions] and 88 [Trend reporting].	Recording and reporting of incidents & FSCA in a system	
		trend report (Article 88)	
Article 10.14	14. Manufacturers shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority of the Member State in which the manufacturer has its registered place of business may require that the manufacturer provide samples of the device free of charge or, where that is impracticable, grant access to the device. Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.	Providing (upon request) the competent authority with all the information and documentation that prove the conformity of the device in an official language of the Member State concerned	
		Providing free samples of the device to the competent authorities at their request, and if this is not possible, providing access to the device	
		Cooperating with the competent authority in order to take any corrective action	
Article 10.15	15. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 30(1) [Electronic system for registration of economic operators].	to register in EUDAMED the sub-contractor who is performing the real & full manufacturing or design	
Article 10.16	16. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law. Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.	Set measures to provide sufficient financial coverage (Directive 85/374/EEC) if a person claims compensation for damage caused by a defective device in accordance with applicable Union and national law	

Article 25.2	Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8) [10 years]: (a) any economic operator to whom they have directly supplied a device; (b) any economic operator who has directly supplied them with a device; (c) any health institution or healthcare professional to which they have directly supplied a device.	Manufacturer must identify to the competent authority for at least 10 years since the device has been placed on the market : a- any economic operator to whom they have directly supplied a device b- any economic operator who has directly supplied them with a device c- any health institution or healthcare professional to which they have directly supplied a device	

Appendix B

Articles 11 and 12 : General obligations of the Authorized representative and Change of authorized representative (respectively)

Regulation 2017/745 of 5 April 2017 regarding Medical Devices	Chapter II, Article 11 : "AuthorisedReprentative"	check list of requirements	OK / NOT OK
Article 11.2	2. The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.	This designation of the foreign manufacturer is the mandate of the authorized representative	
		This designation (mandate) is available only by A written acceptance from the authorized representative	
		This designation (mandate) is effective for all the devices that belongs to the same generic group	
Article 11.3	3. The authorised representative shall perform the tasks specified in the mandate agreed between it and the manufacturer. The authorised representative shall provide a copy of the mandate to the competent authority, upon request	Performing the tasks specified in the mandate and agreed by the manufacturer	
		Providing a copy of the mandate to the competent authority, upon request.	
	The mandate shall require, and the manufacturer shall enable, the authorised representative to perform at least the following tasks in relation to the devices that it covers:	performing at least the following tasks (tasks that should be mentioned in the mandate after being agreed by the manufacturer and the authorized representative)	
Article 11.3.a	(a) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;	The Medical Device have the CE marking	
		The Medical Device have the UE declaration of conformity (Doc)	
		Verifying (where applicable) that appropriate conformity assessment procedure has been carried out by the manufacturer	
Article 11.3.b	(b) keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56 [Certificates of conformity], at the disposal of competent authorities	keeping available a copy of the **technical documentation** of the device at the disposal of competent authorities for at least 10 years (after the last device covered by the EU declaration of conformity has been placed on the market)	

	for the period referred to in Article 10(8) [General obligations of manufacturers];	keeping available a copy of the **EU declaration** of conformity at the disposal of competent authorities for at least 10 years (after the last device covered by the EU declaration of conformity has been placed on the market)	
		keeping available, if applicable, a copy of the **relevant certificate, including any amendments and supplements** (Article 56) at the disposal of competent authorities for a period of at least 10 years (after the last device covered by the EU declaration of conformity has been placed on the market)	
Article 11.3.c	(c) comply with the registration obligations laid down in Article 31 [Registration of manufacturers, authorised representatives and importers] and verify that the manufacturer has complied with the registration obligations laid down in Articles 27 [Unique Device Identification system] and 29 [Registration of devices];	The registration of the authorized representative (Article 31) in EUDAMED	
		Verifying if the manufacturer has performed the necessary registration of the MD in UDI database(Articles 27 and registration of the MD in EUDAMED (article 29)	
Article 11.3.d	(d) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;	Providing (upon request) the competent authority with all the information and documentation that prove the conformity of the device in an official language of the Member State concerned	
Article 11.3.e	(e) forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;	Forwarding to the manufacturer any request for samples or access to the device done by competent authorities	
Article 11.3.f	(f) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;	Cooperating with the competent authority in order to take any corrective action	
Article 11.3.g	(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;	informing the manufacturer immediately about any complaints or reports about suspected incidents	
Article 11.3.h	(h) terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.	Ending the mandate if the manufacturer does not act according to the regulation	
Article 11.4	4. The mandate referred to in paragraph 3 of this Article [Authorised representative] shall not delegate the manufacturer's obligations laid down in Article 10 [General obligations of manufacturers] (1), (2), (3), (4), (6), (7), (9), (10), (11) and (12).	The manufacturer is the one in charge of ensuring the compliance with the obligations of the manufacturer (as per Article 10 (Sections 1, 2, 3, 4, 6, 7, 9, 10, 11 and 12)), those obligations should not be delegated to the Authorized Representative	
		the AR is not responsible for the following tasks (the manufacturer is):	

		Article 10.1 : ensure that the MD has been designed and manufactured according to the MDR requirements	
		Article 10.2 : Establish a risk management system according to Annex I section 3	
		Article 10.3 : Conducts the clinical evaluations according to Article 61 and Annex XIV	
		Article 10.4 : Update the TD of the MD according to Annexes II and III	
		Article 10.6 : establish a CE declaration according to Article 19	
		Article 10.6 : affix the CE marking according to Article 20	
		Article 10.7 : ensure the registration in Eudamed according to article 27	
		Article 10.7 : ensure the registration in Eudamed for the MD according to article 29	
		Article 10.7 : ensure the registration in Eudamed for the economic operator according to article 31	
		Article 10.9 : establish a quality management systems according to the MDR requirements article 10.9	
		Article 10.10 : implement a post-market surveillance according to Article 83	
		Article 10.11 : The device is accompanied by the required information (Section 3 Annex I)	
		Article 10.11 : The devices information are in the official Union language(s) determined by the Member State in which the device is made available	
		Article 10.11 : The label is indelible, easily legible and clearly comprehensible	
		Article 10.12 : Implementing corrective action, withdrawing or recalling if the device placed on the market is no longer in conformity with the regulation	
		Article 10.12 : Informing the distributors the importer and authorized representative of the non-compliant device	
		Article 10.12 : Informing the notified body and the competent authorities of the Member States in which the made the device available if the device present a serious risk	
		Article 10.12 : Informing the notified body about any non-compliance of the device or any corrective action	

Article 11.5	5. Without prejudice to paragraph 4 of this Article [Authorised representative], where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10 [General obligations of manufacturers], the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.	Authorized representative is legally liable for defective devices on the same basis as the manufacturer	
Article 11.6	6. An authorised representative who terminates its mandate on the ground referred to in point (h) of paragraph 3 shall immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.	Informing the competent authority (and where applicable the notified body) when ending the mandate and mentioning the reasons why ending it and because the third-country manufacturer is not compliant with his obligations (article 11.3 (h)).	
Article 11.7	7. Any reference in this Regulation to the competent authority of the Member State in which the manufacturer has its registered place of business shall be understood as a reference to the competent authority of the Member State in which the authorised representative, designated by a manufacturer referred to in paragraph 1, has its registered place of business.	the competent authority of the third-country manufacturer is considered as the one from the AR (id est for ALMS France = ANSM)	
	Chapter II, Article 12 : "Change of Authorised Representative"		
Article 12	The detailed arrangements for a change of authorised representative shall be clearly defined in an agreement between the manufacturer, where practicable the outgoing authorised representative, and the incoming authorised representative. That agreement shall address at least the following aspects:	In case of changing the authorized representative, the manufacturer must draw an agreement that contains all the arrangements of the change, between him and (if applicable) the incoming and the outgoing authorized representative	
Article 12.a	(a) the date of termination of the mandate of the outgoing authorised representative and date of beginning of the mandate of the incoming authorised representative;	this agreement must contain the following aspects :	
		the mandate's ending date of the outgoing authorized representative	
		the mandate's beginning date of the incoming authorized representative	
Article 12.b	(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;	the date until which the outgoing authorized representative may be indicated in the information supplied by the manufacturer	
Article 12.c	(c) the transfer of documents, including confidentiality aspects and property rights	the transfer of documents, including confidentiality aspects and property rights	
Article 12.d	(d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorised representative.	An obligation from the outgoing authorized representative to forward any complaints or reports about a device for which it had been designated as authorized representative even after the end of its mandate	

Article 25.2	Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8): (a) any economic operator to whom they have directly supplied a device; (b) any economic operator who has directly supplied them with a device; (c) any health institution or healthcare professional to which they have directly supplied a device.	Importers must identify to the competent authority for at least 10 years since the device has been placed on the market : a- any economic operator to whom they have directly supplied a device b- any economic operator who has directly supplied them with a device c- any health institution or healthcare professional to which they have directly supplied a device	

Appendix C

Article 13 : General obligations of importers

Regulation 2017/745 of 5 April 2017 regarding Medical Devices	Chapter II, Article 13 : "General obligations of importers"	check list of requirements	OK / NOT OK
Article 13.1	1. Importers shall place on the Union market only devices that are in conformity with this Regulation.	Importer must ensure the device is compliant to the MDR's requirements before placing the product in the market	
Article 13.2.a	(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;	The Medical Device have the CE marking	
		The Medical Device have the UE declaration of conformity (Doc)	
Article 13.2.b	(b) a manufacturer is identified and that an authorised representative in accordance with Article 11 [Authorised representative] has been designated by the manufacturer;	manufacturer is identified	
		the authorized representative has been designated	
Article 13.2.c	(c) the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;	the device is labelled	
		accompanied by the required instructions for use	
Article 13.2.d	(d) where applicable, a UDI has been assigned by the manufacturer in accordance with Article 27 [Unique Device Identification system]. Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and the manufacturer's authorised representative. Where the importer considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which the importer is established.	UDI has been assigned by the manufacturer	
		the device IS NOT marketed if it's not compliant	
		inform the manufacturer and the manufacturer's authorized representative if it's not in conformity	
		inform the competent authority if the device presents a serious risk	
Article 13.3	3. Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.	Importers shall indicate on the device or on its packaging or in a document accompanying the device :	
		their name	
		registered trade name or registered trade mark	
		their registered place of business	

		the address at which they can be contacted	
		Insure that any additional label does not obscure any information on the label provided by the manufacturer.	
Article 13.4	4. Importers shall verify that the device is registered in the electronic system in accordance with Article 29 [Registration of devices]. Importers shall add their details to the registration in accordance with Article 31 [Registration of manufacturers, authorised representatives and importers].	verify that the device is registered in the electronic system EUDAMED	
		Importers shall add their details to the registration in EUDAMED	
Article 13.5	5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I [General safety and performance requirements] and shall comply with the conditions set by the manufacturer, where available.	ensure that storage or transport conditions do not influence the conformity of the device	
		ensure that storage or transport conditions are according to the general safety and performance requirements (Annex I)	
		ensure that storage or transport conditions comply with the conditions set by the manufacturer (where available)	
Article 13.6	6. Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.	keep a register of complaints, of non-conforming devices and of recalls and withdrawals	
		provide the manufacturer, authorized representative and distributors with any requested information	
Article 13.7	7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and its authorised representative. Importers shall co-operate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it is	co-operate with the manufacturer, the manufacturer's authorized representative and the competent authorities to ensure that the necessary corrective action/withdraw/recall if the device in non-compliant	

	taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 56 [Certificates of conformity] for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.	inform the competent authority and, if applicable, the notified body if the device presents a serious risk giving theme details of the non-compliance and of any corrective action taken	
Article 13.8	8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative.	immediately forwarding any received complaints or reports to the manufacturer and its authorized representative	
Article 13.9	9. Importers shall, for the period referred to in Article 10(8) [General obligations of manufacturers], keep a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56 [Certificates of conformity].	keeping a copy of the EU declaration of conformity for at least 10 years	
		Keeping for at least 10 years a copy of any relevant certificate (Article 56) including any amendments and supplements…	
Article 13.10	10. Importers shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request by a competent authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.	cooperate with competent authorities in order to handle the risk of the device made available on the market	
		provide samples to competent authorities or at if not possible grant access to the device	
Article 25.1	Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.		

Article 25.2	Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8): (a) any economic operator to whom they have directly supplied a device; (b) any economic operator who has directly supplied them with a device; (c) any health institution or healthcare professional to which they have directly supplied a device.	Importers must identify to the competent authority for at least 10 years since the device has been placed on the market : a- any economic operator to whom they have directly supplied a device b- any economic operator who has directly supplied them with a device c- any health institution or healthcare professional to which they have directly supplied a device	
Article 30.3	Within two weeks of placing a device, other than a custom-made device, on the market, importers shall verify that the manufacturer or authorised representative has provided to the electronic system the information referred to in paragraph 1.	The Importer must verify that the Manufacturer and the Authorized Representative has done their required registration at the electronic system within two weeks of placing the device on the market	
	Where applicable, importers shall inform the relevant authorised representative or manufacturer if the information referred to in paragraph 1 is not included or is incorrect. Importers shall add their details to the relevant entry/entries.		
Article 16.1	A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:	The obligation of the manufacturer apply to the importer if :	
	a. makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;	If the importer put in the market a device under his name or trade mark (except if he made an agreement with the manufacturer to mention him in the label and keep him responsible for meeting the manufactured requirements)	
	b. changes the intended purpose of a device already placed on the market or put into service;	If the importer changes the intended purpose of the device	
	c. &16.2 : modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.	If the importer modifies the device in such a way that the compliancy might be affected. The following changes are not considered as modification of the device : a- provision b- translation c- further information which is necessary in order to market the device d- changes to the outer packaging e- change of the pack size, if the repackaging is necessary to marketing the device and if the original condition cannot be affected. The activities mentioned above are not considered as modification, However if the importer does them, then he should mention on the device or on its packaging or in a document accompanying the device, the activity he carried out, its	

		name, its trade name or mark, its place of business and the address at which it can be contacted.	
Article 16.3	Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, inter alia, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.	the quality management system of the importer must - ensure an accurate translation of information - ensure that the following activities (provision, translation, further information, changes to the outer packaging, change of the pack size) are performed with the preservation of the original condition of the device and the packaging of the repackaged device is not defective, not of poor quality or untidy. - ensure that the importer is informed of any corrective action taken by the manufacturer	
Article 16.4	At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use.Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.	importer must inform the manufacturer and the competent authority 28 days before placing the relabeled or repackaged device on the market	
		Importer must provide (upon request) to the manufacturer and the competent authority any sample of the relabeled or repackaged device and the instruction of use	
		Importer must submit to the competent authority (within 28 days before placing the device in the market) a certificate issued by a notified body that proves that the quality management system ensure : - an accurate translation of information - that the following activities (provision, translation, further information, changes to the outer packaging, change of the pack size) are performed with the preservation of the original condition of the device and the packaging of the repackaged device is not defective, not of poor quality or untidy. - that the importer is informed of any corrective action taken by the manufacturer	

Appendix D

Article 14 : General obligations of distributors

Regulation 2017/745 of 5 April 2017 regarding Medical Devices	Chapter II, Article 14 : " General obligations of distributors"	check list of requirements	OK / NOT OK
Article 14.2	Before making a device available on the market, distributors shall verify that all of the following requirements are met :		
Article 14.2.a	(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up	The Medical Device have the **CE marking**	
		The Medical Device have the UE **declaration of conformity** (Doc)	
Article 14.2.b	(b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11) [General obligations of manufacturers]	The device is accompanied by the required information supplied by the manufacturer (Article 10 section 11): label, IFU, IN CASE OF STERILE STATUS FOR PACH STERILE PACKAGING	
Article 14.2.c	(c) for imported devices, the importer has complied with the requirements set out in Article 13(3) [General obligations of importers]	The Importer of the device is compliant with (Article 13 section 3) about indicating the importer's contact details on the device or on its packaging or in a document accompanying the device, and ensure that any additional label does not obscure any information on the label provided by the manufacturer.	
Article 14.2.d	(d) that, where applicable, a UDI has been assigned by the manufacturer.	UDI has been assigned to the device by the manufacturer	
Article 14.2	Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.	informing the manufacturer, authorized representative and importer if the device in non compliant	
		not making the device on the market until it's not compliant	
		informing the competent authority of the Member State (ANSM, FR) if the device may present serious risk or if it's falsified	
Article 14.3	3. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.	to get the storage and transport compliant with conditions from manufacturer	

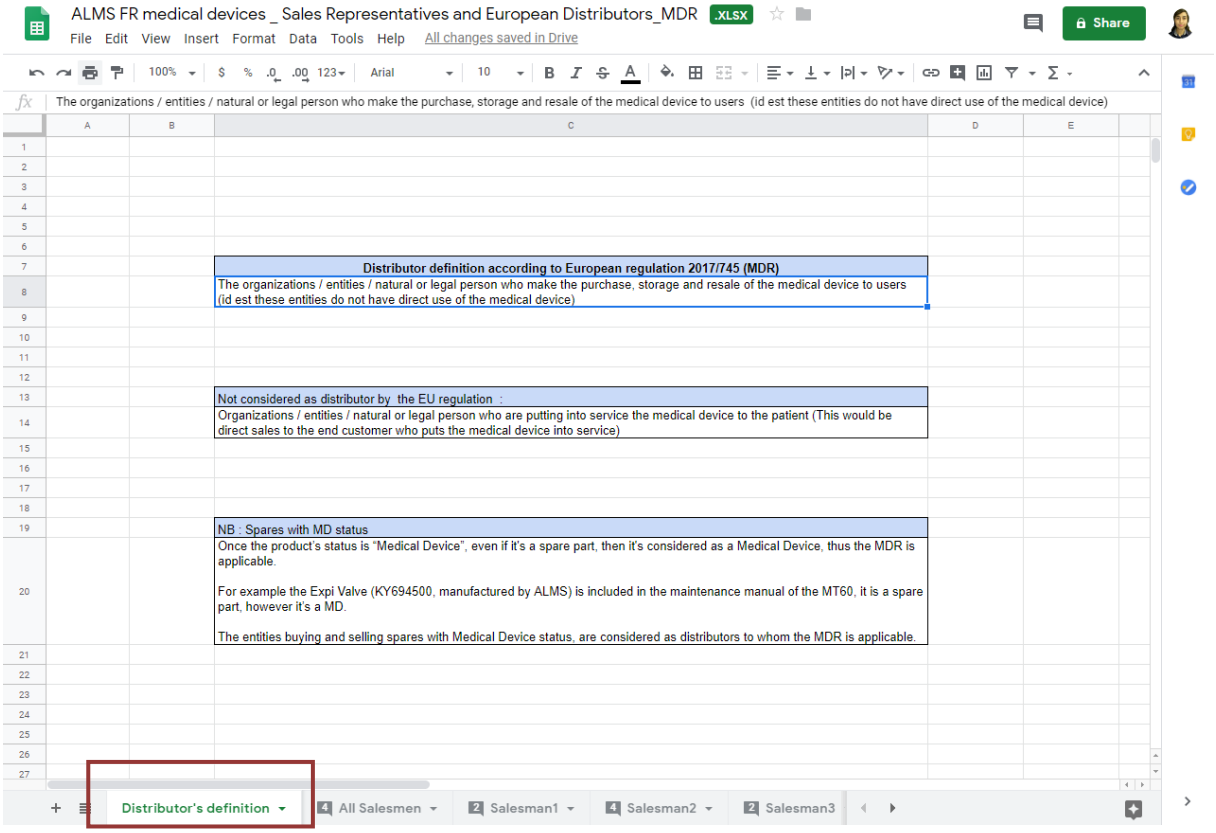
Article 14.4	4. Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer'sauthorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.	Informing the manufacturer, its authorized representative and the importer if the device in not in conformity	
		Cooperating with the manufacturer, its authorized representative, the importer and the competent authorities, in order to bring the MD into conformity, to withdraw it or to recall it	
		Informing competent authorities immediately if the device may present a serious risk, and giving details of the non-conformity	
Article 14.5	5. Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.	Forwarding any received complaints or reports about suspected incidents to the manufacturer or the manufacturer's authorized representative and the importer	
		Keeping a register of complaints, of non-conforming devices and of recalls and withdrawals and providing the manufacturer or the manufacturer's authorized representative, and the importer with any information upon their request	
Article 14.6	6. Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device. Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorisedrepresentative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.	Providing the competent authority upon request with all the information and documentation that prove the conformity of the device	
		Cooperating with competent authorities at their request to take any action that eliminate the risks posed by the device	
		Providing free samples of the device to the competent authorities at their request, or, granting them access to the device	
Article 25.1	Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.	to perform traceability of medical devices distributed by ALMS FR	

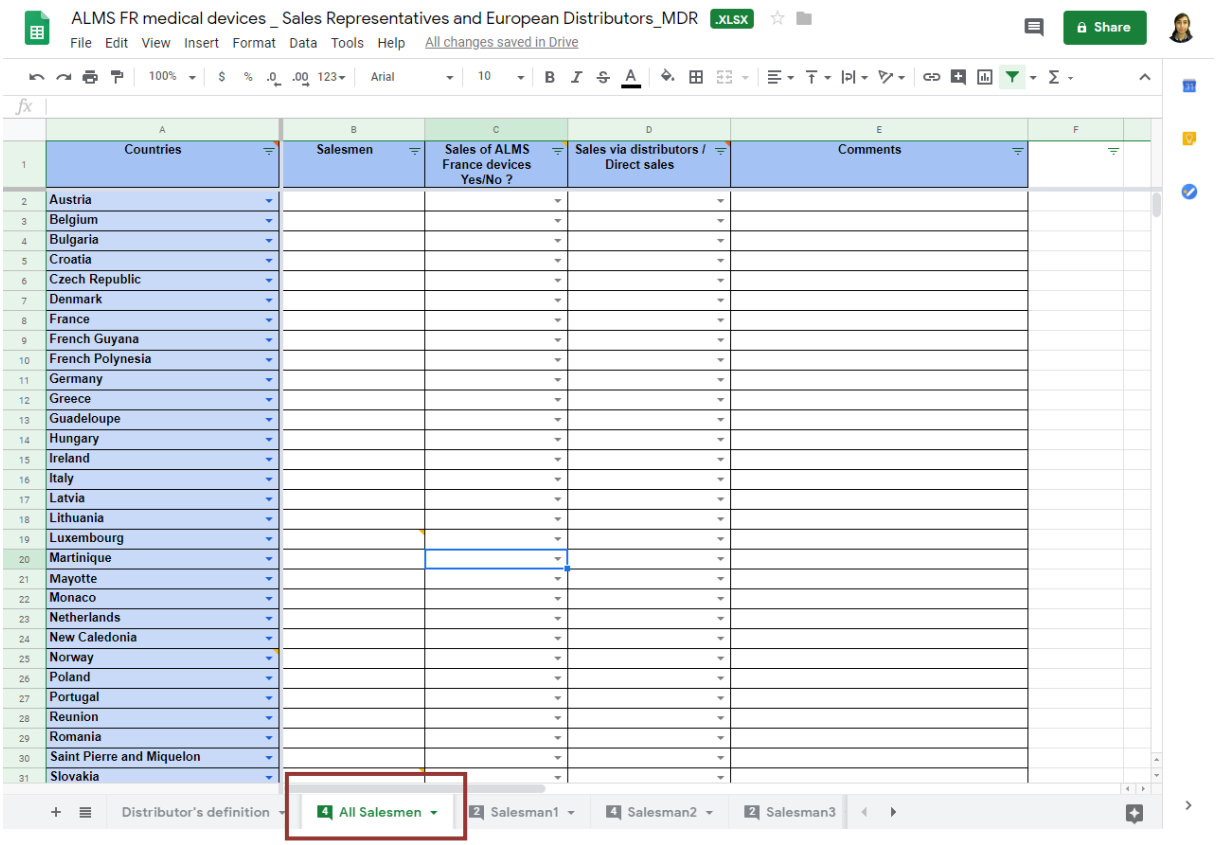
Article 25.2		Distributors must identify to the competent authority for at least 10 years since the device has been placed on the market : a- any economic operator to whom they have directly supplied a device b- any economic operator who has directly supplied them with a device c- any health institution or healthcare professional to which they have directly supplied a device	
Article 16.1	A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:	The obligation of the manufacturer apply to the distributor if :	
	a. makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;	If the distributor put in the market a device under his name or trade mark (except if he made an agreement with the manufacturer to mention him in the label and keep him responsible for meeting the manufactured requirements)	
	b. changes the intended purpose of a device already placed on the market or put into service;	If the distributor changes the intended purpose of the device	
	c. &16.2 : modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.	If the distributor modifies the device in such a way that the compliancy might be affected. The following changes are not considered as modification of the device : a- provision b- translation c- further information which is necessary in order to market the device d- changes to the outer packaging e- change of the pack size, if the repackaging is necessary to marketing the device and if the original condition cannot be affected. The activities mentioned above are not considered as modification, However if the distributor does them, then he should mention on the device or on its packaging or in a document accompanying the device, the activity he carried out, its name, its trade name or mark, its place of business and the address at which it can be contacted.	
Article 16.3	Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, inter alia, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into	the quality management system of the distributor must - ensure an accurate translation of information - ensure that the following activities (provision, translation, further information, changes to the outer packaging, change of the pack size) are performed with the preservation of the original condition of the device and the packaging of the repackaged device is not defective, not of poor quality or untidy. - ensure that the distributor is informed of any corrective action taken by the	

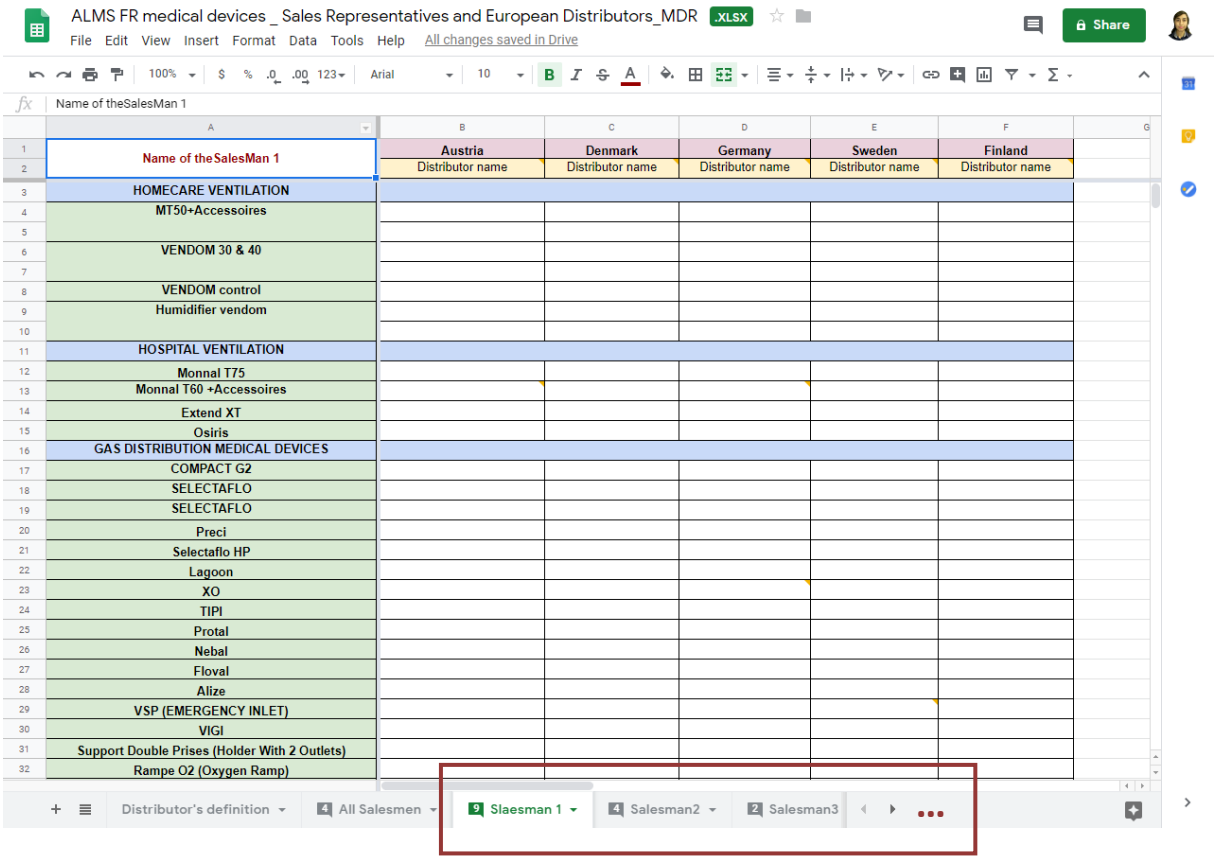
	conformity with this Regulation.	manufacturer	
Article 16.4	At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use.Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.	distributor must inform the manufacturer and the competent authority 28 days before placing the relabeled or repackaged device on the market	
		distributor must provide (upon request) to the manufacturer and the competent authority any sample of the relabeled or repackaged device and the instruction of use	
		distributor must submit to the competent authority (within 28 days before placing the device in the market) a certificate issued by a notified body that proves that the quality management system ensures : - an accurate translation of information - that the following activities (provision, translation, further information, changes to the outer packaging, change of the pack size) are performed with the preservation of the original condition of the device and the packaging of the repackaged device is not defective, not of poor quality or untidy. - that the distributor is informed of any corrective action taken by the manufacturer	

Appendix E

Cartography of the distributors







ALMS FR medical devices _ Sales Representatives and European Distributors_MDR .XLSX

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Name of theSalesMan 1

	A	B	C	D	E	F	G
1	Name of the SalesMan 1	Austria	Denmark	Germany	Sweden	Finland	
2		Distributor name	Distributor name	Distributor name	Distributor name	Distributor name	
3	HOMECARE VENTILATION						
4	MT50+Accessoires						
5							
6	VENDOM 30 & 40						
7							
8	VENDOM control						
9	Humidifier vendom						
10							
11	HOSPITAL VENTILATION						
12	Monnal T75						
13	Monnal T60 +Accessoires						
14	Extend XT						
15	Osiris						
16	GAS DISTRIBUTION MEDICAL DEVICES						
17	COMPACT G2						
18	SELECTAFLO						
19	SELECTAFLO						
20	Preci						
21	Selectaflo HP						
22	Lagoon						
23	XO						
24	TIPI						
25	Protal						
26	Nebal						
27	Floval						
28	Alize						
29	VSP (EMERGENCY INLET)						
30	VIGI						
31	Support Double Prises (Holder With 2 Outlets)						
32	Rampe O2 (Oxygen Ramp)						

Distributor's definition | All Salesmen | Slaesman 1 | Salesman2 | Salesman3