MDS – G10

GUIDANCE ON

LABELLING REQUIREMENTS FOR MEDICAL DEVICES

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DEFINITIONS & ABBREVIATIONS

Definitions

Manufacturer	means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
Authorised Representative	means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Importer	means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.
Distributor	means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.
Establishment	any place of business within the KSA that is involved in the manufacture, and/or placing on the market, and/or distribution of medical devices; or acting on behalf of the manufacturer.
Labelling	means written, printed or graphic matter A. Affixed to a medical device or any of its containers or wrappers. B. Information accompanying a medical device, related to identification, technical description. C. Information accompanying a medical device, related to its use, but excluding shipping documents.
Instructions For Use	means information provided by the manufacturer to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken.
Advertising of Medical Devices	means any form of information, canvassing activity or inducement intended to promote the supply or use of medical devices.
Lay person	individual that does not have formal training in a specific field or discipline. Note: **Medical personnel** in healthcare facilities are **not** considered to be **lay persons**.

Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: - Diagnosis, prevention, monitoring, treatment or alleviation of disease, - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, - Investigation, replacement, modification, or support of the anatomy or of a physiological process, - Supporting or sustaining life, - Control of conception, - Disinfection of medical devices, - Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
In-Vitro Medical Device	means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.
Accessory	means a product intended specifically by its manufacturer to be used together with a medical device to enable that medical device to achieve its intended purpose.
Medical Devices National Registry	is the database of both registered establishments and medical devices the SFDA has authorized to be placed on the KSA market.
National Establishment Registry Number	is the number issued to a person by the SFDA under the establishment registration provisions of the Medical Devices Interim Regulation.

Abbreviations

AR	Authorized Representative
SFDA	Saudi Food and Drug Authority
MDMA	Medical Devices Marketing Authorization
MDNR	Medical Devices National Registry
IFU	Instructions For Use
OEM	Original Equipment Manufacturer
OBL	Own Brand Labeler

INTRODUCTION

Purpose

The purpose of this document is to clarify **labelling requirements for medical devices** such that they comply with the requirements of the Medical Devices Interim Regulation.

Scope

This document applies to the following parties:

- Medical devices **manufacturers**.
- **Authorized representatives** of medical devices manufacturers.
- Medical devices **importers**.
- Medical devices **distributors**.

Background

To obtain MDMA (see the guidance document issued by the SFDA/MDS entitled MDS-G5 Guidance on Marketing Authorization Procedures that is available on the SFDA's website), medical device shall **comply with**:

- The **relevant regulatory requirements** applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA, and
- **Provisions specific to the KSA**, including those **concerning labelling and conditions of supply and/or use.**

Labelling Purpose

The primary purpose of labelling is to:

- **identify the medical device and its manufacturer**,
- describe the device's **intended use** and **performance**,
- describe how the device should be **used**, **maintained** and **stored**, and
- provide information on any **residual device risks**, **warnings**, **limitations** or **contraindications**.

Labelling Meaning and Location

The term '**LABELLING'** is a collective term comprising:

- the **LABEL**,
- **INSTRUCTIONS FOR USE** (sometimes referred to as the operator's manual), and
- any other information that is related to identification, technical description, intended purpose and proper use of the medical device, **excluding** shipping and customs-related documents.

LABEL

Term and Locations	The term '**LABEL'** describes written, printed, or graphic **information** that is: ○ affixed to or appearing on the **medical device itself** (including **electronic display**) ○ on the **packaging** of : ▪ each unit (wrapper) ▪ multiple devices (containers) ○ on a **package insert** (is used where it is **impractical** or inappropriate to affix a label directly on the medical device itself. Impractical means where physical constrains prevent this happening).

INSTRUCTIONS FOR USE (IFU)

Term	The term 'Instructions For Use (**IFU**)' means **information** provided by the manufacturer **to inform** the device **user**: ○ of the medical device's **intended purpose** and **proper use**. ○ of any **precautions** to be taken. **IFU** may **not** be **needed** or may be abbreviated for devices **if** they can be **used safely** and as intended by the manufacturer without any such instructions for use (e.g. walking sticks or simple wound dressings).
Locations	The **preferred locations** for **information** required to be in the **IFU** are the following: ○ on the **device itself** (for the information needed for using the device safely and for its intended purpose) ○ on the **packaging** of: ▪ each unit (wrapper) ▪ multiple devices (containers) (This alternative is used where it is **impractical** placing the IFU on the device itself. Impractical means where physical constrains prevent this happening). ○ in **instruction leaflet** (This is the remaining alternative).

REQUIREMENTS

I. General Rules

Submitting Labelling to SFDA	1.	Labelling provided to SFDA shall be complied with: ▪ the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA (**SFDA requires copies of all labelling as they were submitted and approved by the relevant regulatory authority**), and ▪ the **provisions specific to the KSA** concerning labelling and conditions of supply and/or use. Applicants providing information for MDMA purposes shall submit copies of all labelling, in the format that will be used when the device is marketed within the KSA, to the SFDA website. The SFDA will confirm, in particular, they satisfy requirements in respect of product **identification, language, and tracking** of individual devices through the supply chain.
	2.	Where labelling is provided in Arabic and/or English, it shall be **submitted by the manufacturer**.
Language of Labelling	3.	Where the **user** of the medical device is : ▪ likely to be professionally **qualified**, labelling shall be in **English** ▪ a **lay person**, the LABEL and IFU shall be, wherever feasible, in **both Arabic and English (including that on any display**). Where this is not feasible, the language used on the LABEL and IFU shall be Arabic. In both situations, the text shall be written in terms readily understood by the intended user, commensurate with their technical knowledge, experience, education or training.
Language of Manufacturer's Instructions	4.	**Instructions for the handling, storage, transportation, installation, maintenance and disposal** of the medical devices shall be in **English and, where justified, in Arabic**. The text shall be written in terms readily **understood** by the intended user, commensurate with their technical knowledge, experience, education or training where such work may be undertaken by persons without medical qualification. Where the device is intended to be used by **lay persons**, **instructions for the handling, storage, transportation,**

		maintenance of the medical devices shall be in **both Arabic and English**. The text shall be written in terms readily **understood** by the intended user, commensurate with their technical knowledge, experience, education or training where such work may be undertaken by persons without medical qualification.
Power Supply	5.	Where the device is intended to be connected to an a/c power supply, the label and the IFU shall indicate the nominal **frequency (60 Hertz)** and the **voltage** values with their tolerances for which the devices have been designed. (For information on the national requirement on nominal voltage, see the council of ministers resolution number 324 dated on 20/9/1431 H for the approval of changing the voltage of electricity distribution for residential and commercial establishments in the new areas and for new subscribers in the existing areas from (127/220) volts to the voltage (**230/400**) volt).
Environmental Factors	6.	The **IFU** shall provide information on any measures taken to accommodate the specific non electrical environmental and/or conditions of use encountered in the KSA, such as (a) local operating **temperature** and **humidity** conditions and (b) the level of protection of the devices against **electro-magnetic disturbances**, when applicable.
Medium of Labelling	7.	**Labels** shall be provided in a **human-readable format** but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.
	8.	Where **IFU** are provided to the user **in a non-paper format**, such as downloaded from the manufacturer's website using the internet, the means chosen must be appropriate for, and accessible to, the anticipated user population. Also, the manufacturer shall ensure the user has information on **how to**: ▪ view the IFU. ▪ identify and access the correct version of the IFU use. ▪ obtain a paper version of the IFU. Where the device is intended for use by **lay persons**, the IFU shall be provided in **a paper format**.
Advertising	9.	**Advertising** and marketing information shall be **in English**, or where the device is intended to be used by **lay persons, in Arabic**.
Logo Of SFDA or Another Jurisdiction	10.	Labelling shall **not** include the **SFDA logo nor** the **Establishment National Registry Number,** that is issued by the SFDA through SFDA's **MDNR,** but may include the **Medical Device National Listing Number** issued by the SFDA through SFDA's **MDMA**.
	11.	The SFDA has the right to **request evidence** when labelling includes a **symbol/logo** (e.g. CE Marking) **used by another jurisdiction** to indicate the device complies with the relevant

		regulations of that other jurisdiction.
Note	12.	Please **note** that, the **labelling requirements of Saudi customs** may differ from SFDA requirements of marketing authorisation. Information on customs requirements is available on Saudi customs' website. **However**, SFDA staff will **ensure** that the manufacturing site of the **country of origin**, shown on the labelling of the imported devices, is covered by the documents provided to SFDA through **MDMA submission**.

II. Content of Labelling

	Content	Label	IFU
1	**Name of device** (Trade Name/ Brand Name/ Model Number). Note: Model Number shall be on the IFU if applicable.	Yes	Yes
2	**Name and address of the manufacturer**. (For information on how to determine the legal manufacturer in OEM / OBL cases, see Annex 1)	Yes	Yes
3	Where the device is connected to an a/c **power supply**, an indication the nominal **frequency** (**60 Hertz**) and the **voltage** values with their **tolerances** for which the devices have been designed (see **section I. General Rules, Point 5** in this document).	Yes	Yes
4	If the device is an **IVD** medical device, an indication that the device is for in vitro diagnostic use.	Yes	Yes
5	Where applicable, an indication of any **special storage** and/or handling condition that applies.	Yes	Yes
6	Any **warnings, precautions, limitations** or **contra-indications**.	Yes	Yes
7	The **batch code/ LOT number** or the **serial number** of, to allow post-market action to be taken if there is a need to trace or recall the device. However for accessories of IVD medical device this may be substituted with a **control number** and for software it shall be substituted with a **version number**.	Yes	
8	An unambiguous indication of the **date** until when the device may be used safely, (e.g. on devices supplied sterile or single use disposable devices), where this is relevant.	Yes	
9	The details strictly necessary for a user to **identify the device and its use**.	Yes	
10	Where relevant, an indication of the net **quantity of contents**, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package.	Yes	
11	If the **device is intended for single use**, an indication of that fact.	Yes	
12	If the IVD medical device is intended for **single use** and there is a potential risk of re-use, an indication of that fact.	Yes	
13	Where applicable, an indication that the device contains or incorporates a **medicinal** or **biological substance**.	Yes	

14	If the device is for **use by a single individual** and has been manufactured according to a written prescription or pattern (i.e. it is **custom made**), an indication of that fact.	Yes	
15	If the device is intended for **premarket clinical investigation** only, an indication of that fact.	Yes	
16	If the IVD medical device is intended for **premarket performance evaluation** only, an indication of that fact.	Yes	
17	If the device is intended for **non-clinical research, teaching** or **testing** purposes only, an indication of that fact.	Yes	
18	If the device is intended for **presentation** or **demonstration** purposes only, an indication of that fact.	Yes	
19	The device's **intended use/purpose** including the intended user.		Yes
20	The **performance of the device** intended by the manufacturer.		Yes
21	If the device is **supplied sterile**, instructions in the event of the sterile packaging being damaged before use.		Yes
22	For **IVD** medical device, **test principle**.		Yes
23	For potentially **hazardous devices** or their parts, **warnings** or **precautions** to be taken related to the **disposal** of the device, its accessories and the consumables used with it, if any.		Yes
24	If the device is **reusable**, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization. Information shall be provided to identify when the device shall no longer be reused.		Yes
25	If the device **emits radiation** for medical purposes, details of the nature, type and where appropriate, the intensity and distribution of this radiation.		Yes
26	If the device contains, or incorporates, a **medicinal substance** and/or **material** of **biological origin**, identification of that substance or material, as appropriate.		Yes
27	Specifications the user requires to use the device appropriately, e.g. if the device has a **measuring function**, the degree of accuracy claimed for it.		Yes
28	For devices intended for **use together with other medical devices** and/or general purpose equipment:		Yes

	• information to identify such devices or equipment, in order to obtain a **safe combination**, and/or • information on any **known restrictions to combinations** of medical devices and equipment.		
29	Where applicable, details of any preparatory treatment or **handling of the device before it is ready for use**.		Yes
30	Where relevant, any requirements for **special facilities**, or **special training**, or particular qualifications of the device user.		Yes
31	The information needed to verify whether the device is **properly installed and is ready to perform safely** and as intended by the manufacturer, together with, where relevant: • details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection; • identification of any consumable components and how to replace them; • information on any necessary calibration to ensure that the device operates properly and safely during its intended life span; and • methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing medical devices.		Yes
32	Any **residual risks**, contraindications and any expected and foreseeable **side effects**, including information to be conveyed to the patient in this regard.		Yes
33	For devices intended for **use by lay persons**, the circumstances when the user shall consult with a healthcare professional.		Yes

III. Required Documents

The documents required for a **MDMA submission** are:

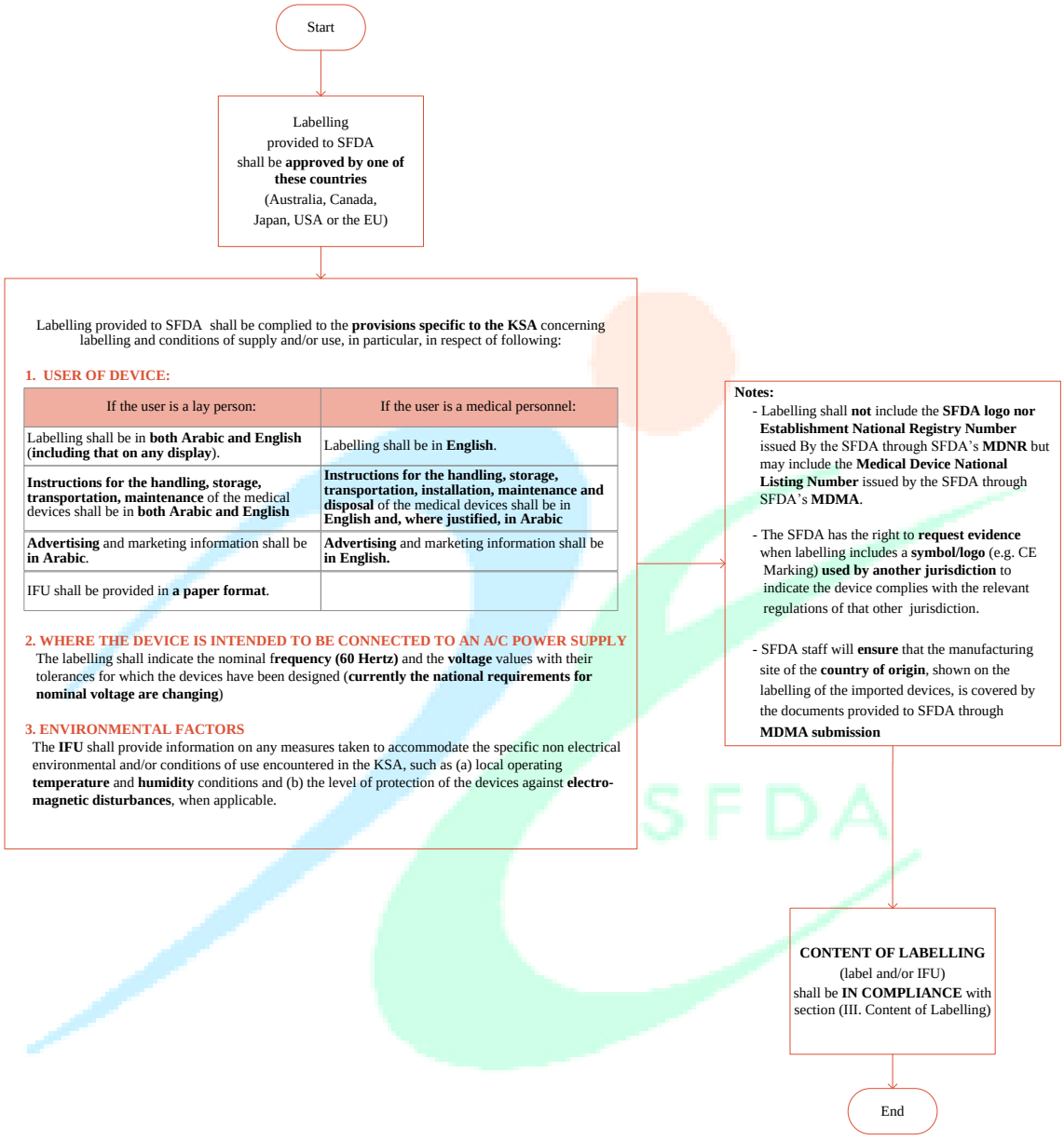
<table>
<tr><th>S/N</th><th>Required Documents</th><th>MDMA electronic application form sections</th><th>Note</th></tr>
<tr><td>1</td><td>A copy of the
LABEL(S) affixed to the device or its wrappers when it is supplied to the KSA.</td><td>Section
(2.1.10)</td><td rowspan="2">▪ If the IFU are not relevant, provide a justification. The justification shall be signed by the manufacturer with its letterhead, signer’s job title, signature date.
▪ See section I. General Rules in this document.
▪ Content of labelling (label and/or IFU) shall be in compliance with section II. Content of Labelling in this document.
▪ Provide labels and IFU of all devices, models and IDs listed in section 2.1.
▪ It is acceptable to provide a label that represent the ranges of the device (e.g. sizes) but the representative label shall be supplemented by a document contains a table that clearly links one product-size to one product ID number, see below table. The supplemented document shall be signed by the manufacturer with its letterhead, signer’s job title, signature date.
Example:
<table><tr><td>Trade Name</td><td>REF (Product ID Number)</td><td>Size (product variable)</td></tr><tr><td>Medical Device</td><td>1234</td><td>5x5cm</td></tr><tr><td>Medical Device</td><td>1236</td><td>10x10cm</td></tr></table>▪ Where the device is intended to be connected to an a/c power supply, provide images of the power supply label, so it can be cross-checked with the A/C Power Supply signed declaration provided in section 2.3.</td></tr>
<tr><td>2</td><td>A copy of the
IFU document intended for KSA users of the medical device.</td><td>Section
(2.1.11)</td></tr>
</table>

			▪ For IVD Kits, all the individual reagent labels shall be provided. ▪ If the device contains **porcine**, an indication of that fact on the labelling.
3	A copy of the **manufacturer's instructions** to **ensure** that the devices intended to be placed on the KSA market will be **correctly stored**, **transported**, **installed**, **maintained** & **disposed** of, and that users can be trained in their proper use and maintenance.	Section (**2.5**)	▪ See **section I. General Rules, Point 4** in this document. ▪ The applicant may also provide additional information that they believe is relevant to this requirement. The additional information shall be signed by the manufacturer with its letterhead, signer's job title and signature date.

4	A copy of the **MANUFACTURER'S ADVERTISING** and marketing material intended for use in the KSA.	Section (**2.6**)	▪ Parties in the supply chain shall **submit** proposed advertising to the SFDA on an **ongoing** basis **not only** for MDMA purposes.
			▪ Manufacturer's advertising and marketing material includes, for example:
			  ▪ written material. (e.g. printed **product catalogue**)
			  ▪ information available on the internet (**manufacturers website**, which is accessible in Saudi Arabia)
			  ▪ information available in electronic form (e.g. **CD**)
			▪ Provide a copy of the manufacturer's advertising and marketing material for **all the devices listed in section 2.1**. It is **acceptable** to **include more devices than is listed in section 2.1**.
			▪ Manufacturer's advertising and marketing material shall contain the following:
			  ○ **name of device**
			  ○ **name of the manufacturer**.
			  ○ **document control reference number.**
			It is **not necessary** to include the **manufacturer address**.
			▪ **If** the manufacturer's advertising and marketing material is :
			  ○ **not available,** provide an **explanation**.

			The explanation shall be signed by the manufacturer with its letterhead, signer's job title, signature date and the date of providing the manufacturer's materials to SFDA. ○ **not required,** provide a **justification**. The justification shall be signed by the manufacturer with its letterhead, signer's job title and signature date. ▪ The manufacturer's advertising and marketing material shall: ○ be in **English**, or ○ where the device is intended to be used by **lay persons**, in **Arabic**. ▪ The manufacturer's advertising and marketing material shall: ○ **NOT mislead** the user regarding the performance of the medical device as specified by the manufacturer. ○ **avoid misleading lay persons**, where the advertising to the general public, including on the internet. ○ include the **relevant information compatible with professional specific needs**, where the advertising to professionally qualified.

IV. Flowchart



ANNEXES

Annex 1

Determination of Legal Manufacturer in OEM /OBL Cases

The legal manufacturer in OEM / OBL cases, where the **EU jurisdiction** has been selected as the basis of the MDMA application, SFDA considers the manufacturer's name which is next to the "**Manufacturer Symbol**  " on the labelling as the legal manufacturer. If this is not applicable, the following documents should be sent to OEM-OBL.MD@sfda.gov.sa:

- copy of conformity assessment certificates based on the used conformity assessment route (i.e. CE certificate, DE certificate, Production Quality Assurance Certificate…etc)
- copy of products' Declaration Of Conformity
- copy of labelling (including the Instruction For Use)
- most recent Audit report (if applicable)

Examples:

Examples for If there is a Manufacturer Symbol	Legal manufacturer considered by SFDA	Examples for If there is NO Manufacturer Symbol	Legal manufacturer considered by SFDA
Logo of manufacturer A  Name and address of manufacturer A Manufactured by manufacturer B Manufactured for manufacturer A	Manufacturer A	Logo of manufacturer A Manufactured for manufacturer A Manufactured by manufacturer B	More documents are required
Logo of manufacturer A  Name and address of manufacturer B Manufactured by manufacturer B Manufactured for manufacturer A	Manufacturer B	Logo of manufacturer A Manufactured for manufacturer B Manufactured by manufacturer A	More documents are required
Logo of manufacturer A  Name and address of manufacturer B Manufactured by manufacturer C Manufactured for manufacturer B	Manufacturer B	Logo of manufacturer A Manufactured for manufacturer B Manufactured by manufacturer C	More documents are required

Logo of manufacturer A  Name and address of manufacturer B Manufactured by manufacturer A Under License of manufacturer B	Manufacturer B	Logo of manufacturer A Manufactured by manufacturer A Under License of manufacturer B	More documents are required
Logo of manufacturer A  Name and address of manufacturer B Manufactured by manufacturer B Under License of manufacturer A	Manufacturer B	Logo of manufacturer A Manufactured by manufacturer B Under License of manufacturer C	More documents are required
Logo of manufacturer A  Name and address of manufacturer B Manufactured by manufacturer B Under License of manufacturer C	Manufacturer B		
Logo of manufacturer A  Name and address of manufacturer B	Manufacturer B		