Medical Device Registration Manual

Finished Import - April 2023

HITco
شرکت تامین سرمایه سلامت
Health Investment Tamin Company

TAMINSHAFAPARS
تامین شفا پارس

Contents

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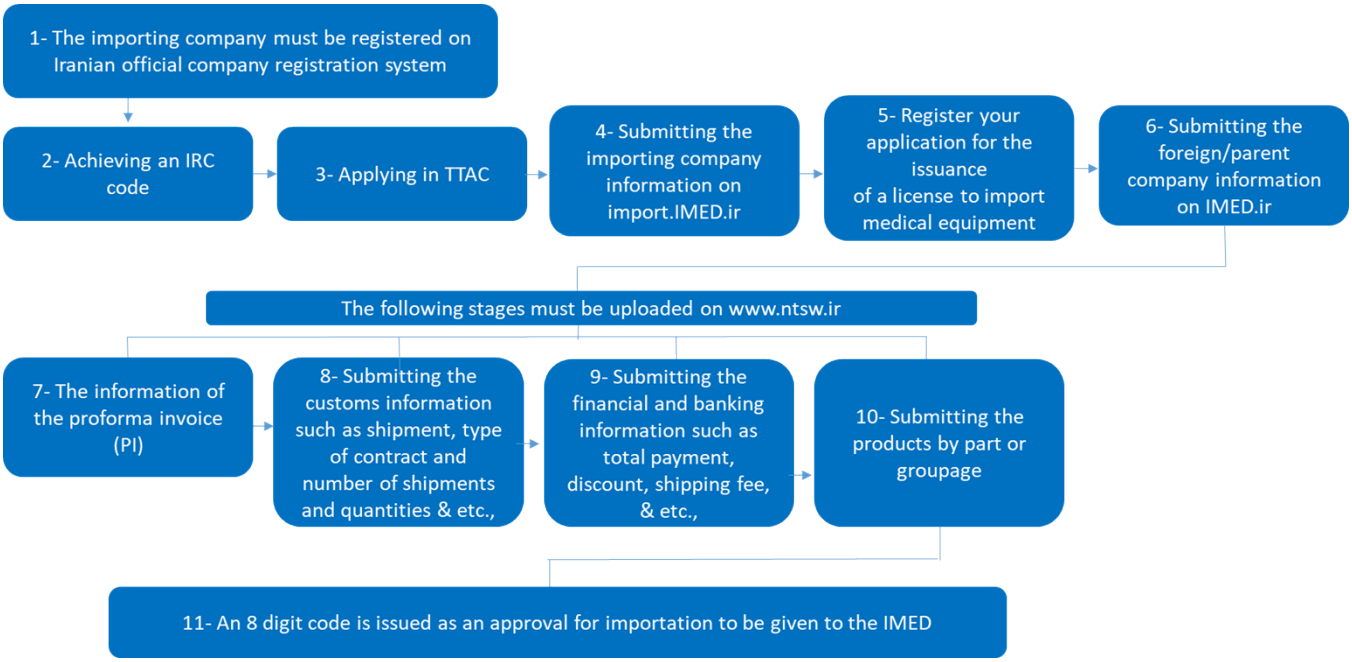
Introduction:

Each product that needs to be produced in Iran requires an IRC Code (Iran Registration Code). This IRC is a unique code for each and every product. In order to obtain the IRC, the products have to be registered in Iran FDA.

Medical Device and consumable Importing requirements

- Obtaining a license from the General Department of Medical Equipment.
- Obtaining an import and export license from Iran's Ministry of Industry, Mining and Trade at https://www.ntsw.ir/
- Presenting the documents to the General Department of Medical Equipment.
- The Importing company must be registered in the Iranian official company registration system at www.irsherkat.ssaa.ir
- Applying for an IRC code, which is a unique identifier for a health-oriented product or a common identification number for pharmaceutical products, medical and laboratory equipment.
- Appointing a technical supervisor or a technical manager approved by the medical equipment committee, in order to carry out scientific and legal supervision, on the import process of medical devices and equipment distribution, by the importer.
- Full compliance of the documents provided with the imported goods.

Medical device importation approval



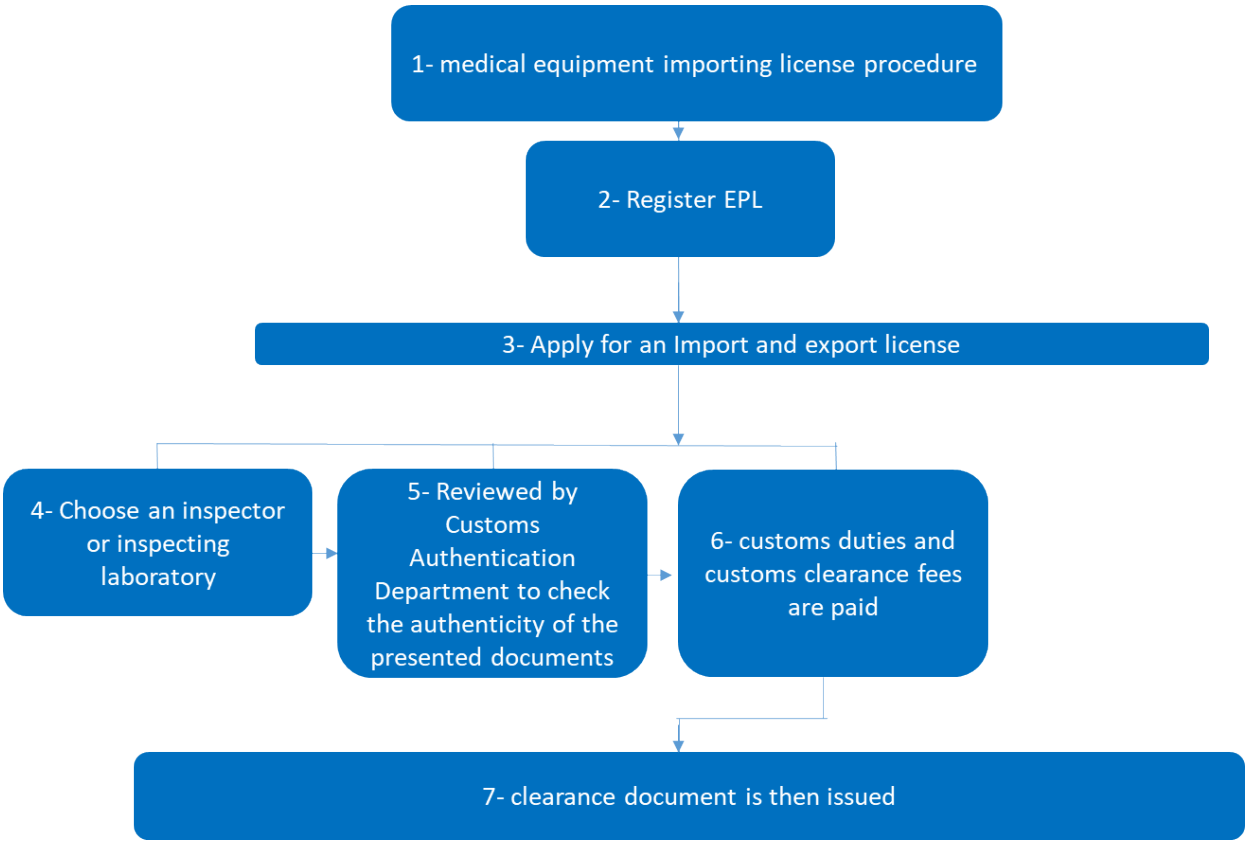
Documentation needed for importing license

- Registering for an IRC (Iran Registration Code) in the Iranian Ministry of Health (MoH)
- For achieving an IRC code:

    - The applicant must sign up for registration on the www.ttac.ir website
    - The applicant must register its importing company on the IMED (www.Imed.ir) which is under the supervision of MOH
    - The applicant must place the information of the placed order (PI) from the foreign/parent company on the Ministry of Industry, Mining and Trade website https://www.ntsw.ir/

- Registering for an IRC (Iran Registration Code) in the Iranian Ministry of Health (MoH)
- Submitting the importing company information on www.import.IMED.ir
- Register your application for the issuance of a license to import medical equipment
- Submitting the foreign/parent company information on www.IMED.ir
- Uploading the following on the Ministry of Industry, Mining and Trade website in order to receive an 8-digit importation approval code.
- The information of the proforma invoice (PI)
- Submitting the customs information such as shipment, type of contract and number of shipments and quantities & etc.,
- Submitting the financial and banking information such as total payment, discount, shipping fee, & etc.,
- Submitting the products by part or groupage

Medical equipment importing license procedure



Procedures and methods of importing medical equipment

After the applicant succeeds in obtaining the medical equipment and consumables importing license, the applicant must go through the following steps in order to be able to import the medical goods to the country and sell them in the domestic market:

- The first step is to obtain permission from the customs and register the EPL (Electronic Packing List) declaration
    - For uploading the EPL:
    - The applicant must have the Final import declaration, bill of lading, copy of commercial card, license, declaration of currency supply, certificate of origin, purchase invoice, catalog and brochure, order registration license, insurance policy, operating license, export license and legal licenses obtained from the Food and Drug Organization and Department of Medical Devices on order to submit the EPL to the customs.

- In the next step, the applicant must go to coc.isiri.gov.ir to obtain a license from the export and import system and select one of the standard experts, inspection companies or laboratory users based on the type of imported goods in order to achieve an import and export license.
- After completing the above steps, the Customs Authentication Department will check the person's information and if the information and documents provided are approved, a registration number will be assigned to the applicant.
- In the next step, imported goods are checked for their compliance with presented documents and declarations, and in case of final approval, the applicant must pay customs duties and customs clearance fees.
- The clearance document is then issued and the owner of the goods can legally clear her goods from customs by going through the rest of the procedures.

Requested documents for importing medical equipment all in one

- Commercial Card
- Mutual agreement/contract between the companies and an approval regarding the registration of the applicant in the system of the General Department of Medical Equipment
- Product label and product Catalog
- GTIN – Global Trade Item Number
- CE & ISO certificates and FDA if available
- Free Sale Certificate (FSC) / Certificate of Exportation
- Letter of Authorization (LOA)
- COA of product/ Test Report/ Clinical investigations and clinical trial reports for the medical device
- Price List
- Art work files (Label, Leaflet, Box)
- Letter of commitment (LOC)
- Market Share / Market History of Product
- Declaration of Conformity (DOC)
- Technical Data Sheet
- MDR report of the medical device if applicable

Essential definitions

CE/International Organization for Standardization (ISO)

CE mean that the manufacturer or importer affirms the goods' conformity with European health, safety, and environmental protection standards. ISO certification is a seal of approval from a third party body that a company runs to one of the international standards developed and published by the International Organization for Standardization (ISO).

Free Sale Certificate (FSC)

You can find the Template of Free sale certificate in the Appendix. The authorized body can issue this certificate for you and you have just to get it signed and approved by the Iran Embassy.

Here are some points which should be noted in Free Sales Certificate:

1. Please make sure that you state the full address and phone number of the manufacturer.
2. The Certificate has to be on a letter head of the authorized body.
3. Please make sure that all pages of the certificate are signed, stamped and bundled together.
4. Please note that you have to submit a Free Sales Certificate per Manufacturing Plant. For example, if you have part of your product manufactured in a factory in Italy and you have some products manufactured in France, you will require 2 separate Free Sale Certificates, one for the manufacturing plant in Italy and one for the manufacturing plant in France.
5. Please make sure that you indicate the Brand name in front of each product in the Product Table.

Letter of Authorization(LOA)

One of the most important step is to submit a true copy of a legalized “LOA”. We need to receive an authorization letter based on we will be authorized for registration, manufacturing under license, marketing, distribution and sales your products as your business partner. You can find the sample of LOA in the Appendix.

Registration process in Iran for under license products:

A) Distribution Registration:

The following documents are needed for partnership/distribution registration:

- LOA
- LOC
- CE/ISO

B) Product registration in MoH

require the following documentation (samples are within the appendix):

1. Free Sale Certificate (FSC) / Certificate of Exportation
2. COA of product/ Test Report
3. Price List
4. Art work files (Label, Leaflet, Box)
5. Market Share / Market History of Product
6. Declaration of Conformity (DOC)
7. Catalogue
8. GTIN of Product
9. Technical Data Sheet

COA of product/ Test Report

Certificate of Analysis (COA) is a document that communicates the results of a scientific test done on a product such as food or drugs. The COA also lists the chemicals used in the product's manufacturing and testing and is created to ensure all important regulations are met and complied with.

Declaration of Conformity (DOC)

It is a formal declaration by a manufacturer, or the manufacturer's representative, that the product to which it applies meets all relevant requirements of all product safety directives applicable to that product.

GTIN of Product

The Global Trade Item Number (GTIN) is a globally unique 14-digit number used to identify trade items, products, or services.

APPENDIX 1- Free Sales Certificate

Date:

Name of Licensee: Name of Manufacturer:

Address: Address:

Tel: Tel:

Fax: Fax:

Website: Website:

Free Sales Certificate

This is to certify that the products of company *(Please name your company)*, under …… Brand *(Name your Brand)* are freely sold in large scale in …… *(Countries names)*, and are freely and in large scale exported to other countries.

Products: *(List your products in details; please insert a table for this part)*

APPENDIX 2- Letter of Authorization(LOA)

[To be printed on Company Letterhead of Product Owner]

Letter of Authorization

[Date]

Subject: Letter of Authorization for *[Name of Authorized Representative}*

To: ISLAMIC REPUBLIC of IRAN

Ministry of Health and Medical Education National Medical Device Directorate TEHRAN-IRAN

We, *[Name of Product Owner],* as the Product Owner, hereby authorize *[Name of Authorized Representative]* as the *[exclusive I Non-exclusive}* representative to prepare and submit applications of the medical devices to the Ministry of Health and Medical Education of Iran on our behalf.

This authorization shall apply to the following medical devices:

[List containing the name of the medical products]

[Name of Authorized Representative} is authorized by *[Name of Product Owner]* for the registration, promotion, sale, distribution, marketing and service and support our products in the territory of Iran.

This authorization commences on the date of signing and is valid for *[NO. OF Years/Months]*

from *[Start Date]* for *[End Date],* If you have any questions, please contact us at *[Email Address].*

Product Owner Address: *[Address],*

[Telefax Number], [Email Address]

Authorized Representative Address: *[Address],*

[Telefax Number}, [Email Address]

[Full Name and Title of Senior Company Official] [Signature]

[Company stamp]

APPENDIX 3 - Letter of Commitment (LOC)

To: ISLAMIC REPUBLIC OF IRAN

MINISTRY OF HEALTH

Treatment assumes & MEDICAL EDUCATION

Medical Equipment Department

TEHRAN-IRAN

Commitment Letter

We, **Company name**, declare of the following items

Company name

Address:

Email : Tel:

This company confirms the technical and professional liability and capability of the representative company in the fields of technical support, installation, startup training, testing for acceptance and calibration and operation of equipment and after sales services.

1- This company accepts the responsibility regarding all after sales services and support of the equipment, equipment related consumable and semi-consumable accessories for the machines

sold to Iran for duration of at least 10 years after installation.

2- This company undertakes to follow all regulations and obligations specified by CE, FDA Procedure and other competent authorities and regarding the post market phase for medical equipment sold to IRAN.

3- This company Guarantees the machines sold to Iran at least for 1 year from the date of

Installation.

Note: It is necessary to mention that in special cases, depending upon the type of product, it is possible to extend this duration upon agreement.

4- In case of transferring our representation in IRAN, this company undertakes to inform the Department of Medical Equipment of the Ministry of Health, immediately and in the form of written documentation, and take the necessary actions towards continuously supporting the previously sold When it comes to termination of current authorization contract or changing representation, the new representative company which has been appointed by the company shall enjoy the capability in providing after sales services in conformity with products under representation (and in accordance with number of sold products manufactured in Iran until its termination time or

changing of current representation). Otherwise Iran Ministry of Health and Medical Education and Treatment assume its right to prevent new representation activity or registry in IRAN.

Note: Definition of after sales services (corresponding to Medical Equipment by – law, Article 32) is hereby attached.

5- At the time of termination of authorization Contract or its change, equipment or spare parts (whose production date is not exceeded more than five years) and consumable items holding authentic expiration date (At least 40% is remained from the production date up to its expiration date) available in former representative Company's stock which were sold according to the previous price to former representatives which shall be taken back or Compensate damages and losses inflicted upon former representative about the mentioned products.

6- All Current representative obligations and offering after sales services of sold equipment will be rested with manufacturing company or new representative if the representation changes.

Medical Equipment By- law, Article 32:

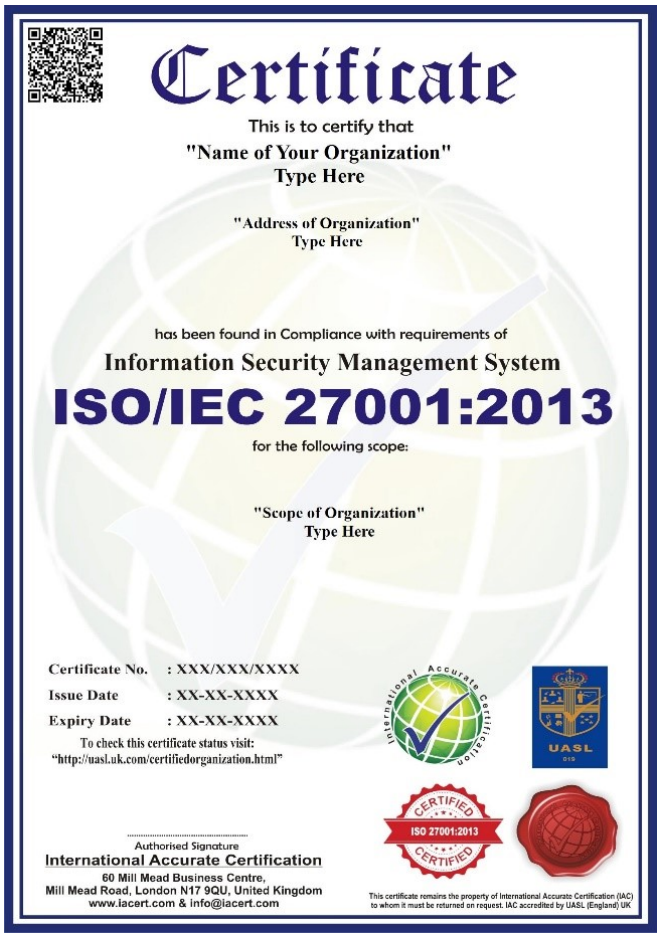
After sale services consist to a set of measures and engagements undertaken by local or foreign producer (or his/her legal representative), after selling medical equipment, and in order to attain desired performance and respecting safety principles, during the engagement duration

Note- The expected measures include installation, operating, acceptance test performance, Training, guarantee, spare part supply, partial fixing and over hall, calibration, improvement and upgrade, product tracing, client request satisfying, modification measures performance and product recall.

Sincerely Yours,

General Manager

APPENDIX 4- CE/International Organization for Standardization (ISO)



Certificate

This is to certify that

"Name of Your Organization"
Type Here

"Address of Organization"
Type Here

has been found in Compliance with requirements of

Information Security Management System

ISO/IEC 27001:2013

for the following scope:

"Scope of Organization"
Type Here

Certificate No. : XXX/XXX/XXXX
Issue Date : XX-XX-XXXX
Expiry Date : XX-XX-XXXX

To check this certificate status visit:
"http://uasl.uk.com/certifiedorganization.html"

Authorised Signature
International Accurate Certification
60 Mill Mead Business Centre,
Mill Mead Road, London N17 9QU, United Kingdom
www.iacert.com & info@iacert.com

CERTIFIED ISO 27001:2013 CERTIFIED

UASL

This certificate remains the property of International Accurate Certification (IAC) to whom it must be returned on request. IAC accredited by UASL (England) UK

APPENDIX 5- International sales

International [product] sales

Country	Year	Sales amount(PCS)	percentage

APPENDIX 6 – Declaration Letter

Manufacturer Letterhead

Reference No.

Issuance Date:

To: Islamic Republic of Iran Ministry of Health and Commerce

Declaration Letter

We, (Manufacturer Name) having office at ……., Tel ……., Fax ……., Email: ……., registered No ….. , hereby confirm that (supplier name) is authorized to sell our Products to **Health Invest Tamin Co. (HITCO)** represented by Mr. Ali Babaie as the CEO, having office at No 56, Alvand Street, Tehran, Iran, Postal Code: ……., Phone: +98 (21) …… Fax: +98 (21) ….., Email:…… , website: www.hitcoholding.com , Registration number: …. which is the **Exclusive Distributor** of our supplier for the following Products with the following brands in Iran territory.

Product name	**Brand name**	**Manufacturer name**

Dispute Resolution: Any difference, dispute, controversy and/or claim should be settled in accordance with the Arbitration Rules of the International Chamber of Commerce in Paris/ France

Termination: It will be after the expiry of LOA.

This agency agreement is valid for 5 years.

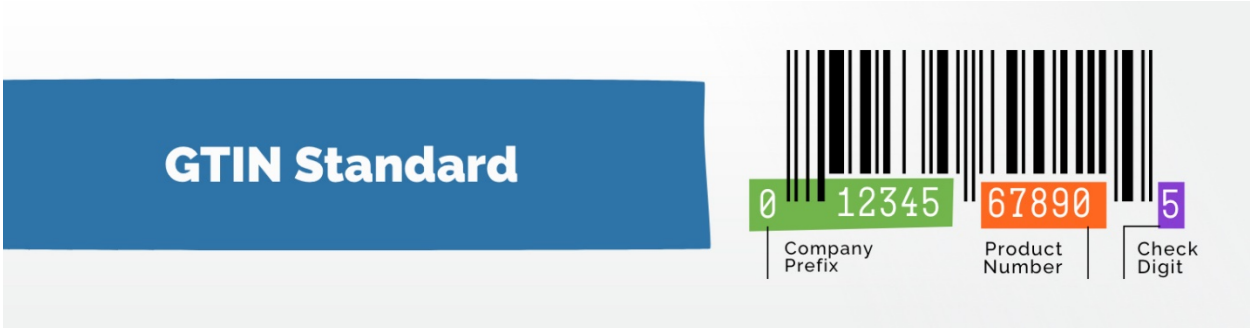
Sincerely yours,

Signature

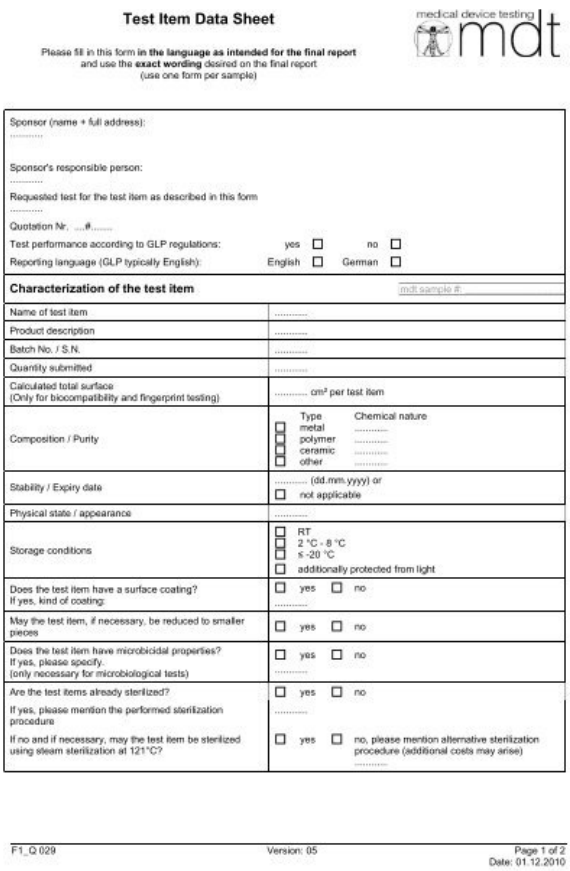
Name

Title

APPENDIX 7 – GTIN



APPENDIX 8 – Technical Data Sheet



Test Item Data Sheet

medical device testing mdt

Please fill in this form **in the language as intended for the final report** and use the **exact wording** desired on the final report (use one form per sample)

Sponsor (name + full address):	
Sponsor's responsible person:	
Requested test for the test item as described in this form	
Quotation Nr. ....#.....	
Test performance according to GLP regulations:	yes ☐ no ☐
Reporting language (GLP typically English):	English ☐ German ☐
Characterization of the test item	mdt sample #
Name of test item	.....
Product description	.....
Batch No. / S.N.	.....
Quantity submitted	.....
Calculated total surface (Only for biocompatibility and fingerprint testing)	..... cm² per test item
Composition / Purity	Type / Chemical nature ☐ metal ..... ☐ polymer ..... ☐ ceramic ..... ☐ other .....
Stability / Expiry date	..... (dd.mm.yyyy) or ☐ not applicable
Physical state / appearance	.....
Storage conditions	☐ RT ☐ 2 °C - 8 °C ☐ ≤ -20 °C ☐ additionally protected from light
Does the test item have a surface coating? If yes, kind of coating:	☐ yes ☐ no .....
May the test item, if necessary, be reduced to smaller pieces	☐ yes ☐ no
Does the test item have microbicidal properties? If yes, please specify. (only necessary for microbiological tests)	☐ yes ☐ no .....
Are the test items already sterilized?	☐ yes ☐ no
If yes, please mention the performed sterilization procedure	.....
If no and if necessary, may the test item be sterilized using steam sterilization at 121°C?	☐ yes ☐ no, please mention alternative sterilization procedure (additional costs may arise) .....

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APPENDIX 9 – Product Importing Application Form

Product Importing Application Form

1-Product Information

Product (Trade) name (as used in the country of origin)

Active Substance (s):	
form:	
Route of Administration:	
Container. closure and administrative device (s):	
Pack sizes and strengths used in the country of origin:	
Shelf Life period:	
Shelf lifer (after first opening container):	
Storage conditions :	

2- Manufacturer

Marketing Authorization Holder (Name Address & Country):	
Number and Date of the first Marketing Authorization / Renewal	
Manufacturer of Finished Product (Name Address & Country):	

License Holder of Finished product (Name , Address & Country):	

Flow – chart indicating the different sites involved in the Manufacturing process. Packaging & Release of the medicinal product:

Manufacturer of the Active Substance (s) (Name. Address & Country) :	

List the active substance(s) and the excipient (s)

Components	Formula	IUPAC	Function	Quantity	Unit	Reference

3- Hazards identification

Hazard designation

4- First – aid measures

Inhalation Skin contact Eye contact Ingestion

5- Fire – fighting measures

Suitable extinguishing media Unsuitable extinguishing media Additional information

6- Accidental release measures

Personal precautions
Environmental precautions

7- Handling and storage

Information for safe handling
Information about protection against explosions and fires
Further information about storage conditions

8- Exposure controls and personal protection

Components with critical values that require monitoring at the workplace (exposure limits)
Personal protective equipment General protective and hygiene measures
Respiratory protection
Hand protection
Eye Protection
Body Protection

9- Physical and chemical properties Image + Reference + COA

Form: Color: Odor:

Relevant safety date Boiling point / rang: Vapor pressure: Densing: Solvent – sparation test: Solubility in water: PH Value: Flow time: Viscosity:

10- Stability and reactivity

Conditions to avoid

Materials to avoid

11- Toxicological information

Toxicological test LD50/LC50 values that are relevant for classification

12- Ecological information

Details on elimination (Persistence / degradability)

Additional ecological information Additional ecological data Specification: Value / dosage

13- Disposal considerations

14- Side effect(s):

15- Regulatory information

Classification according to EEC directives Danger symbol and danger designation

Hazard – determining components of labeling

Risk - Phrases

Safety - Phrases

National regulatory information
Regulation on inflammable liquids

Emission control act

Water pollution classification

16- Other information

Further information R- phrases of components

This is to certify that the information contained herein is true and correct. Name and title of responsible official in the company: Signature of responsible official in the company : Date and Stamp : Full Address :

17- Official Documents

a) Free Sale Certificate (FSC) Yes□ No□

b)Good Manufacturing Practice (GMP) Certificate Yes□ No□□

c) List of company branches , if any …….

d) International Certificates (FDA , CE , …….) Yes□ No□

e) List of export countries …….

f) Clinical Trial (Study)
Declare abstract:

18 - Sample of original product's label .

APPENDIX 10 – Initial application form for registration of medical device products

Initial application form for registration of medical device products (Domestic manufacturing, importing products)

Applicant company name:

Product brand name:

1. Application of the product:

2. Type of request:

Registration and import □ Registration and production □Contract production □ Undergraduate production□ Extension of construction license □

Product Specifications:

Complete product formulation (Components) with names and amounts of active ingredients and Excipients (separately):

Active and Excipients	CAS no.	Quantity/ ml	Function	Concentration w/w%	Manufacturer company/country