Medical Device Registration Manual

Technology Transfer - May 2023

HITco
شرکت تامین سرمایه سلامت
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Contents

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1. 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. Contract manufacturing is referred to transferring the knowledge and using the facilities of manufacturing companies in other countries. This manual is to better explain the procedure of contract manufacturing or under license manufacturing.

1.1. Purpose The purpose of compiling this manual is to explain how to issue a medical equipment registration license, which is a form of contract manufacturing with international companies and other countries.

1.2. Scope This manual is for applicants for the production of medical equipment and supplies, with the aim of technology transfer.

1.3. Terms and definitions

1.3.1. **General Administration/Ministry of Health***:* The Department/office in charge of the supervision and evaluation of medical equipment and supplies

1.3.2. **Technical committee:** Technical committee of medical equipment and supplies

2. Production of medical equipment and supplies with the aim of technology transfer:

Contract manufacturing with foreign countries is referred to a production that is carried out with the aim of technology transfer and transferring the knowledge according to the local conditions in the country during a specific period.

2.1 The terms and conditions of Contract Manufacturing

The related product must comply with all points referred to in the medical device registration regulations and instructions and the registered product must meet the basic requirements in terms of safety and performance.

2.1.1 The registered product or transferred technology must be up to date with the latest technology. Please be noted that technologies or devices that have been discontinued for any reason will not be subject to this regulation.

2.1.2 The manufacturing of the products must create an acceptable added value (resulting a reduction in the finished price of the product and also the production must create and increase job opportunities) in addition to causing the improvement in quality and creating a platform to increase quality competition amongst the local manufacturers.

2.1.3 The parent company must own the technology itself. Meaning that the device must have been already designed and produced by the parent company. Please be noted that the products that are manufactured under the license with third party or are only assembled by a foreign company, will not be subject to this regulation

2.1.4 The registered product for under license manufacturing must have valid certifications such as FDA of the United States, CE of the European Union, and ISO 13485, etc.,

2.1.5 Establishing a quality management system in the domestic/local company's production line for all products based on ISO 13485 and obtaining a valid ISO 13485 certificate for C and D risk class goods from competent authorities.

2.1.6 Establishing the R & D unit in the domestic/local company and providing documentation of scientific research progress in each of the production stages and ensuring continuous quality with the world's latest technology.

2.1.7 The manufacturer's commitment to exporting the product and providing the product export protocol based on the latest agreed schedule within the time frame of the General Administration/ Ministry of Health.

2.1.8 The operational plan and timing of technology transfer should include all the steps until the achievement of the term "Made in Iran" according to instruction No. 01- WI PR - which needs to be approved by the technical committee.

2.1.9 The manufacturer is responsible for assuring the compliance of the essential safety and performance requirements and guaranteeing this is the manufacturers responsibility.

3. List of documents required for proposing to the technical committee

3.1. Memorandum of cooperation between two companies.

3.2. Valid approvals of the parent company for the device

3.3. Time table of technology transfer including the complete set of the stages related to production by mentioning the manufacturing and packaging locations, the number of production and imports in each phase and how to control the quality of the product in each phase.

Providing the infrastructure specifications required for production by the Iranian company, including a complete description of the production process, testing and quality control of goods in accordance with

valid international standards, including providing all quality control instructions and checklists and production processes. After reviewing the above documents, the issue will be raised in the technical committee for a vote.

4. List of documents required for each phase of contract manufacturing

4.1. A valid contract between two companies that has been approved by the embassy/chamber of commerce (before the start of the first phase).

4.2. Announcing the names and specifications of all the materials, tools and devices needed to complete the production, packaging, sterilization and labeling process by manufacturing companies and manufacturing countries (before the start of each phase).

4.3. A complete performance report of work progress stages (before starting each phase).

4.4. The Registration and attachment of documents required for registration of medical devices according to instruction No. 18 WI--GD

5. Important websites

5.1. Ministry of Industry, Mining and Trade at https://www.ntsw.ir/

5.2. Iranian official company registration system at www.irsherkat.ssaa.ir

5.3. IMED (www.Imed.ir) which is under the supervision of MOH

6. Requested documents for importing medical equipment all in one

6-1 Commercial Card

6-2 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

6-3 Product label and product Catalog

6-4 GTIN – Global Trade Item Number

6-5 CE & ISO certificates

6-6 Free Sale Certificate (FSC) / Certificate of Exportation

6-7 Letter of Authorization (LOA)

6-8 COA of product/ Test Report

6-9 Price List

6-10 Art work files (Label, Leaflet, Box)

6-11 Letter of commitment (LOC)

6-12 Market Share / Market History of Product

6-13 Declaration of Conformity (DOC)

6-14 Technical Data Sheet

6-15 A comprehensive SOP of the whole production process

6-16 The EMC/IEC or Bio-compatibility test results of the medical device from a certified Laboratory

6-17 The test result of clinical study performed by company itself and the MOH reference laboratory based on the specific standard of the medical device.

6-18 BOM of the medical device with price and part consumption per a device

6-19 Brand registration of the parent company for the registered product

6-20 ISO13485/GMP certificate for the manufacturing company

6-21 Gantt chart of the manufacturing time-line

7. 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.

8. 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:

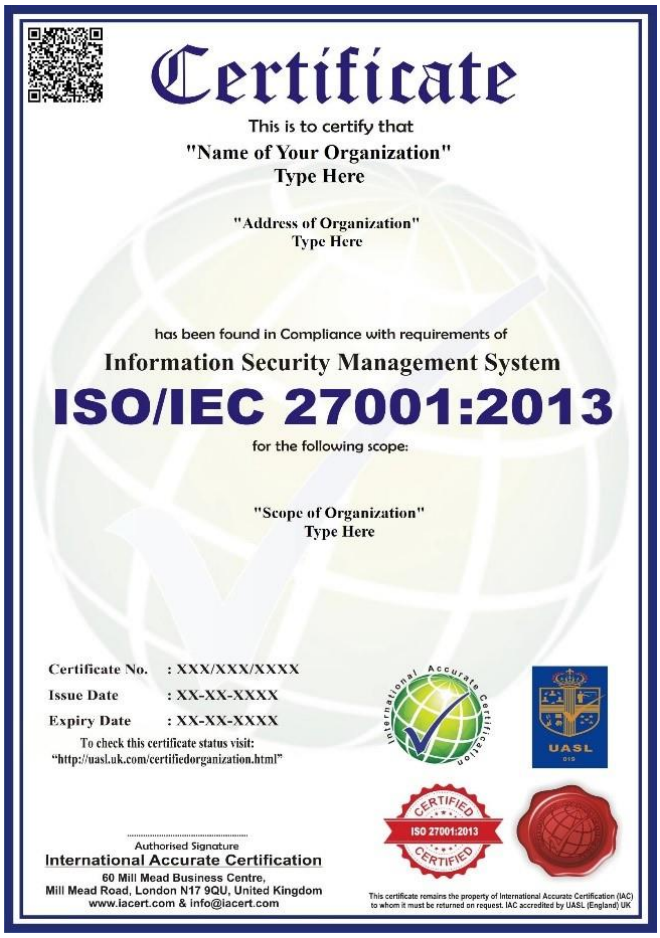
After sale services consist to a set of measures and engagements undertaken by local or foreign producer (or his/her legal representative), after selling medical equipment, and in order to attain desired performance and respecting safety principles, during the engagement duration

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.

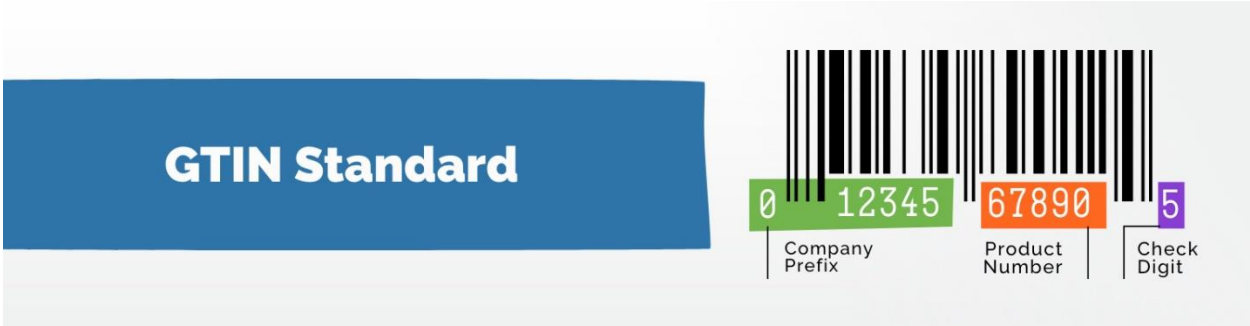
Sincerely yours,

Signature

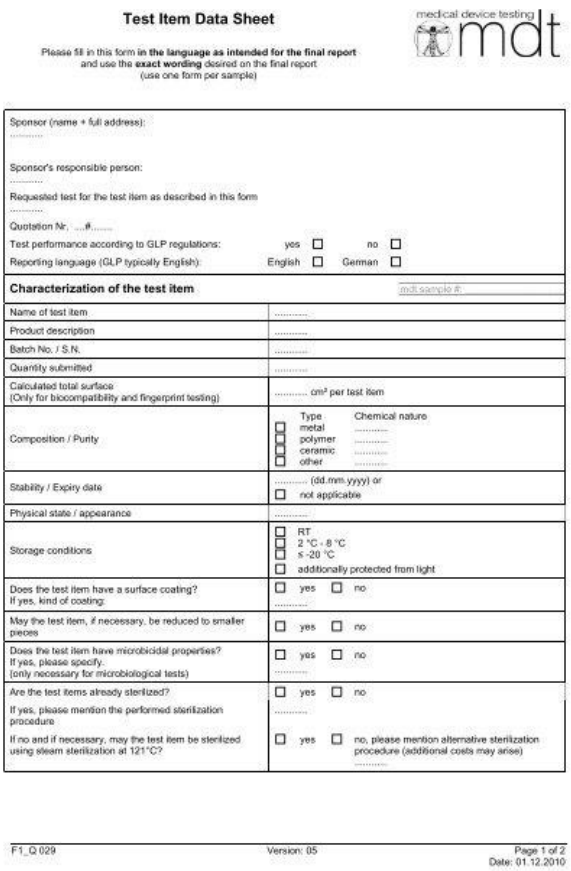
Name

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