ISLAMIC REPUBLIC OF IRAN
MINISTRY OF HEALTH AND MEDICAL EDUCATION
MEDICAL EQUIPMENT QUALITY AND PRICE REGULATORY DEPARTMENT

APPLICATION FOR A MEDICAL DEVICE REGISTRATION

Device Registration Number	

(Official use only)

Date (dd/mm/yy)	

1. DEVICE NAME

Device Name as it appears on label	
UMDNS Code	
UMDNS Term	

2. NAME AND ADDRESS OF MANUFACTURER AS IT APPEARS ON THE LABEL

Company Name
Street Address/P.O Box : City: Province/State: Postal/Zip Code: Country:
Contact Name and Title :
Telephone No.: Fax No.
E-Mail Address :

3. NAME AND ADDRESS OF ORIGINAL EQUIPMENT MANUFACTURER (OEM) (if applicable)

Company Name	
Street Address/P.O Box : City: Province/State: Postal/Zip Code: Country:	
Contact Name and Title :	
Telephone No.:	Fax No.
E-Mail Address :	

4. DEVICE CLASSIFICATION

IRAN Classification	A		EU Classification	I		US FDA Classification	I	
	B			IIa			II	
	C			IIb			III	
	D			III				

5. DEVICE CATEGORY

Anesthesiology		Neurology	
Cardiovascular		Obstetrics & Gynecology	
Dental		Ophthalmology	
Ear, Nose & Throat		Orthopedics	
Gastroenterology & Urology		Physical Medicine	
General & Plastic Surgery		Radiology/Imaging	
General Hospital			

6. DOES THIS DEVICE CONTAIN A DRUG?

Yes ____ No ____

IF YES

Generic Name of Drug:
Brand / Trade Name of Drug:
Drug Manufacturer:

7. PURPOSE/INTENDED USE

A description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented*: [Note: Failure to supply an appropriate level of detail may result in the application being rejected.]*

8. CONTRA-INDICATIONS

Details informing the users and/or patient and allowing the medical staff to brief the patient on any contra-indications, warnings and any precautions to be taken (where appropriate): *[Note: Failure to supply an appropriate level of detail may result in the application being rejected.]*

9. DEVICE DETAIL

Please provide the following information, as applicable to registration application type, and where applicable for each component device, part or accessory. (Add Additional Copy if necessary)

Name of Device, Components, Parts and/or Accessories as per product label	UMDNS Code	Model or catalogue number	Unit Price

10. In addition to items 1 to 9, of the Device Registration Application following information is requested, please indicate (X) which of the relevant information requirements listed below are included as attachments to this application. For details regarding content and format please refer to the GUIDANCE FOR "APPLICATION FOR A MEDICAL DEVICE REGISTRATION"

Cover Page	
Executive summary	
Table of contents	
Device Description (principles of operation & materials used in construction and packaging, describing each of the functional components of the device, with labeled pictorial representation of the device in the form of diagrams, photographs or drawings.)	
Design Philosophy	
Marketing History	
List of Standards	
Method of Sterilization (if applicable)	
Summary of Safety and Effectiveness Studies (for class C and D only)	
Risk Management Report (for class C and D only)	
Material Specifications (for class C and D only)	
Labeling material	
Quality Management Certificate (ISO 13485)	
FDA Approval	
CE Approval	

We, the manufacturer, signed and stamped all documents which are attached and hereby certify that the information provided on this application and in any attached documentation is correct, complete and guarantee the quality of the products are exported to Iran. If any false data are found, we assume legal responsibility, and hold responsibility for all the consequences arising thereafter and this is grounds for refusal to issue registration certificate.

Name of Signing Official:_____

Title:	Managing Director		Sales Manager	
	Regulatory Affairs Manager		Other(Specify):_____	

Signed: _____ Date:_____

GUIDANCE FOR "APPLICATION FOR A MEDICAL DEVICE REGISTRATION"

Item 1: DEVICE NAME

- ***UMDNS Code and Title*:** UMDNS is an international controlled vocabulary for medical devices created and maintained by ECRI. It consists of terms (descriptors) and codes for categories of medical devices that permit classification and retrieval of information at various levels of specificity.
  For more information, or to license the use of UMDNS, please contact ECRI's UMDNS department at +1 (610) 825-6000, ext. 5524; fax +1 (610) 834-1275; e-mail umdns@ecri.org, or visit ECRI's Web site at www.ecri.org.

Item 4: DEVICE CLASSIFICATION

- Check classification of device according to European Directive 93/42/EEC or US FDA Rules and Iran's Medical Device Classification rules which is defined according to GLOBAL HARMONIZED TASK FORCE (GHTF), SG1/N015R22 proposed document (at web site www.ghtf.org).
  IRAN has four classes of medical devices which generally correspond to EU's four classes, as illustrated in the following table:

Iranian Medical Device Classification		European Council Directive 93/42/EEC (MDD)
Class D	Generally Corresponds to	Class III
Class C	Generally Corresponds to	Class IIb
Class B	Generally Corresponds to	Class IIa
Class A	Generally Corresponds to	Class I

Item 10:

- ***Cover Page***

- ***Executive summary* :**
  This section requests summary of all documentation which is provided in one or two pages.

- ***Table of contents***

- ***Device Description* :**
  This section requires a general description of the device, including its principles of operation, and of the materials used in its construction and packaging. Each of the functional components of the device must be described, with labeled pictorial representation of the device in the form of diagrams, photographs or drawings.
  Other information necessary to provide a thorough description of the device must be included. For example, for an implant, a description must be provided of the anatomical location of the device in the body, including any attachment mechanism for the device. Diagrams, illustrations or photographs of the implant in situ should also be supplied.
  The materials used in the device and packaging must be specified. At a minimum, this will include all materials in direct contact with the user or patient. However, other materials of a significant nature must also be specified.
  If the device contains a medicinal substance or drug, a description of the substance and its technical requirements must be provided.

- ***Design Philosophy*** **:**
  This section requests a description of the features that enable the device to be used for the medical conditions and purposes for which it is manufactured, sold or represented by the manufacturer. To satisfy this requirement, a brief description of the design philosophy and performance specifications for the device should be provided, linking them to the claimed indications for use. References and comparisons with appropriate previous versions or generations of the device should be presented. A tabular format is preferred for this comparison.
  In the event that the use of the device is self-evident to the intended user, the customary or most frequent conditions or uses of the device should be summarized.
  This section should include an overview of the purposes and principles of operation for the device and a summary of the method of its use and operation, unless these instructions are not required for the safe, effective use of the device. Details on the strength of materials and the accuracy, sensitivity and specificity of the device should also be supplied.
  The physical aspects of the device, including packaging, operational capabilities and the processing of inputs and the resultant outputs, must be provided. This should include a summary comparison of the design input parameters (operation specifications) with the resultant performance specifications (design output characteristics).

- ***Marketing History*** **:**
  A summary of the marketing history of the device is requested. This would include a summary of special access requests made to the Programme and the outcome of these requests. In addition, the manufacturer must provide a list of countries where the device is currently being sold and the total number of units sold in those countries. A summary of reported problems with the device and details of any recalls in those countries is also required.

- ***List of Standards*** **:**
  The manufacturer is required by this section to submit a list of standards applied, in whole or in part during the design and manufacture of the device. The full title, version or identifying number, date and responsible agency of each standard must be provided in a tabular format.

- ***Method of Sterilization (if applicable)*** **:**
  The manufacturer is requested to provide a description of the sterilization method used and the packaging used to maintain sterility. This must include the type of sterilization process, the level of sterility assurance and an attestation that the process has been properly validated.
- ***Summary of Safety and Effectiveness Studies (for class C and D only)*** **:**
  This section requests a summary of all studies that the manufacturer relies on to ensure that the device meets the safety and effectiveness, as well as the conclusions drawn from those studies by the manufacturer. This includes a summary of all preclinical physical testing, such as stress, fatigue, wear and shelf life, all biocompatibility testing and the results of all animal and previous clinical investigations.

- ***Risk management Report (for class C and D only)*** **:**
  This section requires a risk management, comprised of an analysis and an evaluation of the risks inherent in the use of the device, as well as the risk reduction measures adopted to satisfy safety and effectiveness requirements.
  The manufacturer must identify the individual or organization that carried out the risk analysis. The method of risk analysis must be appropriate for the device and the level of risk involved.

- ***Material Specifications (for class C and D only)*** **:**
  This part of the application must provide details of material identifications and specifications, including raw materials and components. Information must include complete chemical and physical characterization of all component materials. The chemistry and polydispersity of custom-made polymers or resins must be provided, such as main chain structure, cross-link density and ratio of co-monomers.

- ***Labeling material*** **:**
  Labeling materials include:
  - labels on the device and its packaging
  - Instructions for use
  - Other literature or training materials
  - Instructions for installation and maintenance
  - Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform

- ***Quality Management Certificate (ISO 13485)***

- ***FDA Approval***

- ***CE Approval***