نامه درخواست ثبت وسیله تشخیصی آزمایشگاهی پزشکی (IVD)

متقاضی باید فرم زیر را در سربرگ شرکت تکمیل نموده و پس از مهر و امضای مدیرعامل به همراه مدارک لازم جهت ثبت به اداره کل تجهیزات پزشکی ارائه نماید.

بسمه تعالی

جناب آقای مهندس سعیدرضا شاهمرادی
مدیر کل محترم اداره تجهیزات پزشکی

باسلام
احتراماً، به پیوست فرم ثبت وسیله تشخیصی آزمایشگاهی پزشکی (IVD) تکمیل شده توسط کمپانی ..... کشور .....در خصوص ..... (نام وسیله) به همراه سایر مدارک لازم جهت بررسی و طرح در کمیته ثبت تقدیم می گردد.
همچنین این شرکت با شناسه شماره ..... در اداره کل تجهیزات پزشکی ثبت گردیده و آقای / خانم ..... به عنوان مسئول فنی این شرکت جهت پاسخگویی به سوالات فنی وعلمی کارشناسان آن اداره محترم معرفی می گردد .

نام و نام خانوادگی مدیرعامل
مهر و امضا

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

APPLICATION FOR AN IVD 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	ListA		US FDA Classification	I	
	B			ListB			II	
	C			Self Testing			III	
	D			Others				

5. DEVICE CATEGORY

Clinical Chemistry & Toxicology		Immunology	
Hematology		Molecular Diagnostics & Genetics	
Pathology		General Laboratory	
Microbiology		Others	

6. PURPOSE/INTENDED USE

A description of the 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.]*

7. 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	Principle (e.g. Elisa, photometry, chemiluminecence, …)	Number of Tests (for reagents)	Unit Price

8. **In addition to items 1 to 7, 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 AN IVD 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 or Special Microbiological State or State of Cleanness (if applicable)	
Adequate Performance Evaluation Data	
Statement Regarding Compliance with The Common Technical Specifications (CTS) (for class C and D)	
Risk Management Report (for class C and D only)	
Material Specifications and Information on the Origin of Materials (if applicable)	
Labeling Material	
Quality Management Certificate (ISO 13485)	
FDA Approval	
CE Approval	
Manufacturer's Declaration of Conformity	

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 AN IVD MEDICAL DEVICE REGISTRATION"

Item 1: DEVICE NAME

- ***UMDNS Code and Title*:** UMDNS (Universal Medical Device Nomenclature System) 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 98/79/EC or US FDA Rules and Iran's Medical Device Classification rules which is defined according to GLOBAL HARMONIZED TASK FORCE (GHTF), SG1/N045:2008 final document (at web site www.ghtf.org).

Item 8:

- ***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 include.
  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.

- ***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.
  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.

- ***Adequate Performance Evaluation Data*** **:**
  Adequate performance evaluation data showing the performances claimed by the manufacturer and supported by a reference materials, the known reference values, the accuracy and measurement units used, such data should originate from studies in a clinical or other appropriate environment or result from relevant biographical references. These data should include parameters like precision, accuracy, reportable range, sensitivity, specificity, carry over and traceability to reference material. The standards and protocols used should be mentioned.

- ***Statement Regarding Compliance with The Common Technical Specifications (CTS) (for class C and D only)***
  In these specifications appropriate performance evaluation and re-evaluation criteria, batch release criteria, reference method and reference materials are established.

- ***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 and Information on the Origin of Materials (if applicable)*** **:**
  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. In the case of devices containing tissues of human origin or substances derived from such tissue, information on the origin of such material and on the condition in which it was collected.

- ***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 or user, including instructions for any procedure the patient or user is expected to perform

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

- ***FDA Approval***

- ***CE Approval***

- ***Manufacturer's Declaration of Conformity***