APPLICATION FOR MANAGEMENT SYSTEM CERTIFICATION

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ANNEX A – Application for the Performance of Management System Certification for Medical Products (Manufacturers and Trading / , Distribution / Technical Support Companies) in accordance with the standard ISO 13485:2012

Company : _____

Please note with ☒

Manufacturer ☐	If YES,	**IVD 98/79** ☐		**MDD 93/42** ☐		**AIMDD** ☐	
Production outsourced?	☐	If YES, 100%	☐	Subcontractor's activity			
Trading ☐							
Technical support / After Sales Service ☐							

In which of the following technical areas belong the medical devices your company produces / distributes / offers after sales services :

General non-active, non-implantable medical devices	☐
Non-active implants	☐
Devices for wound care	☐
Non active dental devices and accessories	☐
Non-active medical devices other than specified above	☐
General active medical devices	☐
Devices for imaging	☐
Monitoring Devices	☐
Devices for radiation therapy and thermo therapy	☐
Active (non-implantable) medical devices except those specified above	☐
General active implantable medical devices	☐
Implantable medical devices other than specified above	☐
Reagents and reagent products, calibrators and control materials for one and / or more of the following: Clinical Chemistry, Immunochemistry (Immunology), Hematology / Hemostasis / Immunohematology, Microbiology, Infectious Immunology, Histology / Cytology, Genetic Testing	☐
In Vitro diagnostic Instruments and Software	☐
In Vitro Diagnostic Medical Devices other than specified above	☐
Medical Devices Incorporating medicinal substances	☐
Medical Devices utilizing tissues of animal origin	☐
Medical Devices Incorporating derivates of human blood	☐
Medical Devices utilizing micromechanics	☐
Medical Devices utilizing nanomaterials	☐
Medical Devices utilizing biological active coatings and / or materials or being wholly or mainly absorbed	☐

The company assures that :

- It undertakes the responsibility to fulfil the obligations imposed by approved Quality Management System
- It undertakes the responsibility to maintain the approved quality system adequate and efficacious
- It undertakes the responsibility to implement and maintain a systematic procedure for monitoring the experience gained from the use of these products and to take the necessary measures for the implementation of any corrective actions required. This obligation includes also the notification of the competent authorities of the following incidents immediately on learning of

  - any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
  - any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer

_____	_____	_____
Date	Name	Signature / Stamp