TÜVNORD

APPLICATION FOR MANAGEMENT SYSTEM CERTIFICATION

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ANNEX A - Application for the Performance of Quality Management System Certification for Medical Devices (Manufacturers and Trading / Distribution / Technical Support/Services Companies) in accordance with the standard EN ISO 13485 and CMD ΑΥ8/1348/2004 (ΦΕΚ 32Β/2004 as modified with the Δ3(α)4822/2025)

Company: _____

Please check the ROLE of the Organization under the Regulatory System:

☐ **Manufacturer**
SRN: ……..
If YES, ☐ **MDD 93/42/EEC (Legacy Devices Only)** ☐ **(EU) 2017/745 MDR** ☐ **IVDD 98/79** ☐ **(EU) 2017/746 IVDR**

☐ Is production process sub-contracted;
If YES, Describe Subcontractor's Activities ……..

☐ **Importer**
SRN: ……..
☐ **Trade**
☐ **Technical Support**

☐ **Distributor**
☐ **Trade**
☐ **Technical Support**

Activities:

☐ **Production**
☐ **Trade**
☐ **Distribution**
☐ **Storage**
☐ **Installation and Servicing**
☐ **Other services (*Specify services*):**

_____
_____
_____

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MANUFACTURERS ONLY

PRODUCTS	**Group (MDx)**	**Class** (I, Is, Im, Ir, IIa, IIb, III)	Sterilized (Yes: Y / No: N)	**Comments** (e.g.sterilization method)
Medical Devices Technical Areas (IAF MD 09)				
A. Non Active Medical Devices				
General, non-active, non-implantable medical devices				
Non-Active Implants				
Devices for Would Care				
Non-active medical devices except for those specified in the other technical areas of the main Technical Area “Non-Active Medical Devices”				
B. Active Medical Devices				
Software				
Devices for imaging. Product categories covered by the Technical Area: Devices utilizing non-ionizing radiation				
C. In Vitro Diagnostic Medical Devices	**Group (IVx)**	**Category (ABCD)**		
Reagent and Reagent products, calibrators and control materials for Clinical Chemistry.				

FOR MANUFACTURERS/TRADING / SERVICE COMPANIES

D. Parts and Services		**Comments** *(Please described product category, activities and services)*
Raw materials	☐	
Distribution Services	☐	
Maintenance Services	☐	
Transportation services	☐	
Consulting services related to Medical Devices, packaging services etc.	☐	

Note:

1. All above areas in **section A, B, C** are covered by accredited certification EN ISO 13485 per product group described (Manufacturing)
2. The activities described in **section D** are covered by accredited certification EN ISO 13485 for all Product Groups (Trade and Services)

(Annex A19/8 of the Certificate 185-9, ESYD)

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The company assures that:

- It undertakes the responsibility to fulfil the obligations imposed by approved Quality Management System under the Regulatory System applied

- It undertakes the responsibility to maintain the approved quality system adequate and effective

- 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 the responsibility to **immediately inform the competent authorities in accordance with the requirements of Regulations (EU) 2017/745, (EU) 2017/746** if the following incidents come to its attention:

  - 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 related to the performance and safety characteristics of the Medical Device that may lead to an incident under the previous sub-paragraph or to a serious hazard, and for which a recall procedure of the Medical Device may be initiated.

Date	Name	Signature/ Stamp

After filling out the application form, please send it via e-mail to:

keconomidi@tuv-nord.com, medicalgreece@tuv-nord.com