MEDICAL DEVICES CERTIFICATION ADDITIONAL APPLICATION FORM

The information given on this form is transmitted directly to the section of the certification. Incorrect information given in the application form may result in the preparation of false document. The information provided is incorrect and / or the company is not responsible for the lack of obligations to live. Make sure the information is correct and confirm.

What is the Scope of the Medical Devices Quality Management System?	RISK CLASS			
***Indicate your Risk Class according to the technical field.**	HIGH (D) ☐	MEDIUM-HIGH (C) ☐	MEDIUM-LOW (B) ☐	LOW (A) ☐

Please mark the Main Technical and Technical Areas.

Main Technical Areas	Technical Areas	Risk Class
☐Non-active Medical Devices Table A.1.1	☐General non-active, non-implantable medical devices (M01)	B
	☐Non-active implants (M02)	B
	☐Devices for wound care (M03)	B
	☐Non-active dental devices and accessories (M04)	C
	☐Non-active medical devices other than specified above (99)	B-C
☐Active Medical Devices (Non-Implantable) Table A.1.2	☐General active medical devices (M11)	C
	☐Devices for imaging (M12)	C
	☐Monitoring devices (M13)	B
	☐Devices for radiation therapy and thermo therapy (M14)	C
	☐Active (non-implantable) medical devices other than specified above (M1199)	B-C
☐Active Implantable Medical Devices Table A.1.3	☐General active implantable medical devices (AIMD 100)	D
	☐Implantable medical devices other than specified above (AIMD 100-00)	C-D
☐In Vitro Diagnostic Medical Devices (IVD) Table A.1.4	☐Reagents and reagent products, calibrators, and control materials for: (IVD0110)	
	☐- Clinical Chemistry	D
	☐- Immunochemistry (Immunology)	C
	☐- Haematology/Haemostasis/ Immunohematology	C
	☐- Microbiology	C
	☐ Infectious Immunology	B
	☐- Histology/Cytology	C
	☐- Genetic Testing	B
	☐IVD Instruments and software IVD medical devices other than specified above(IVD 0111)	C
	☐IVD medical devices (IVD 0199)	B-C
☐Sterilization Method for Medical Devices Table A.1.5	☐Ethylene oxide gas sterilization (EOG) (10)	B
	☐Moist heat (20)	B
	☐Aseptic processing (30)	B
	☐Radiation sterilization (e.g., gamma, x-ray, electron beam) (40)	B
	☐Sterilization method other than specified above (Explain) (99)	B
☐Devices incorporating/Utilizing Specific Substances/ Technologies Table A1.6	☐Medical devices incorporating medicinal substances (MDS 7001(10))	C
	☐Medical devices utilizing tissues of animal origin (MDS 7002(20))	C
	☐Medical devices incorporating derivates of human blood (MDS 7003(30))	D
	☐Medical devices utilizing micromechanics (MDS 7006(40))	B
	☐Medical devices utilizing nanomaterials (MDS 7008(50))	C
	☐Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed (MDS 7009(60))	C
	☐Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above. (MDS 7010(00))	C
	☐Raw materials (10)	C

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☐Parts or services Table A1.7	☐Components (20)	B
	☐Subassemblies (30)	A-B
	☐Calibration services (40)	B
	☐Distribution services (50)	A-B
	☐Maintenance services (60)	B
	☐Transportation services (70)	B
	☐Other services (80)	A-B

Design:	☐ ***YES*** ☐ ***Out of scop***
Process Information	☐ ***Metal Processing*** ☐ ***Plastic processing*** ☐ ***Glass, ceramic processing*** ☐ ***Textile processing*** ☐ ***Biotechnology*** ☐ ***Chemicals*** ☐ ***Sterilization*** ☐ ***Packaging*** ☐ ***Clean Room*** ☐ ***Software*** ☐ ***Electronic card*** ☐ ***Installation, technical service*** ☐ ***Others, define*** ……

Please define the following processes providing externally or internally. If there is any external process please also define the address

1. *Production Site*: ☐ **Internal** ☐ **External**

Please mention if it is outsourced:
Firm Name _____
Address _____

2. *Sterilization, If an*): ☐ **Internal** ☐ **External**

Firm Name _____
Address _____
Method ☐ ***ETO Sterilization*** ☐ ***Moist hea*** ☐ ***Aseptic processing***
☐ ***Radiation sterilization (e.g. gamma, x-ray, electron beam***
☐ ***Other*** _____

3. *Packaging, If any:* ☐ **Internal** ☐ **External**

Firm Name _____
Address _____
Validation _____

4. *Storage*: ☐ **Internal** ☐ **External**

Firm Name _____
Address _____

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Please define critical suppliers with the processes, if any

Critical supplie 2: ***Addres*** ***Process***	***Critical supplier 2:*** ***Address:*** ***Process:***

A)	***Information about the company and organization***				
1-	*If your company is already ISO 9001:2015, ISO 14001:2015, ISO 45001, the system certifications available?*	☐ ISO 9001 ☐ ISO 45001 ☐ ISO 20000	☐ ISO 14001 ☐ YOK/ NO ☐ DİĞER/OTHERS:		
2-	*For Medical Devices Management System (TCYS) the name of the person who has been assigned to the implementation and maintenance of the profession and what contact information?*				
3-	*ISO 13485 system operation date*				
4-	*Is 13485 audit carried out by an independent organization or is there a client / approval / certificate have? The organization and the certificate name?*				
5-	**Product class?*(2017/745/EU) *In Vitro Diagnostic Medical Device (IVDR)(2017/746/EU)	☐ I ☐ Is ☐ Im ☐ Ir ☐ IIa ☐ IIb ☐ III ☐SINIF A ☐SINIF B ☐SINIF C ☐SINIF D			
6-	*Is it an Implantable product?*	☐ Evet /Yes	☐ Hayır/No		
7-	*Intended use of the product?*				
8-	*List of products*				
9-	Technical characteristics of the product (Please define critical product and process information.)				
10-	Porudtc Harmonized Standards				
11-	Has there been any negative incidents regarding the product in the last year? (Customer complaints, recalls, etc.) If your answer is Yes, please explain in detail.				
12-	Number of personnel in the company				
	a- Production:	**d- Warehouse:**	**g-Top Management:**	**j- Other (Explain):**	
	b- Design/R&D):	**e- Sterilization:**	**h-Quality Management:**	**k- Subcontractor:**	
	c- Sales :	**f- Packaging:**	**i-Satınalma (Purchasing):**	**l-Part time:**	
B)	**Information about product/service**				
13-	*Outside the scope of activities associated with the company's certification, address (s) if available please provide information about these places.*				

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14-	*Please indicate the scope of products and services offered in the company. Please write your products. Please send it to production flow charts.*			
15-	**Question IAF MD 9 Parts and Services Table B.1**		**Yes**	**No**
	Is the product a nearly finished and assembled medical device? (i.e., it is intended to be used for a medical purpose and only needs packaging and/or labeling)			
	Is the product intended to be a component/part of a medical device?			
	Is the organization contracted to carry out any activities that are regulated by a medical device regulation (e.g., relabeling, remanufacturing of other medical devices)?			
	Is the product supplied sterile?			
	Does the product contain software developed by the client organization or a supplier?			
	Is "Design and Development" in the scope of the ISO 13485 certification (e.g., when public law permits exclusion of design and development which is the case very often for low-risk medical devices)?			
	Is the product (Raw Materials, Parts, Components, Subassemblies, Maintenance Services, or Other Services) intended to support associated medical devices?			

Customer's
Full name, signature, date