

**QUESTIONNAIRE FOR THE PRELIMINARY IDENTIFICATION AND EVALUATION FOR THE  
CERTIFICATION OF THE MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM**

<b>Name of the organization:</b>	
Address (for each location):	
Contact person for the preparation of audit activities of the management system	Name, surname:
	Phone:
What is the type of medical device (s)?	
What is the category of the medical device?	General non-active, non-implantable medical devices: <input type="checkbox"/> Non-active devices for anaesthesia, emergency and intensive care <input type="checkbox"/> Non-active devices for injection, infusion, transfusion and dialysis <input type="checkbox"/> Non-active orthopedic and rehabilitation devices <input type="checkbox"/> Non-active medical devices with measuring function <input type="checkbox"/> Non-active ophthalmologic devices <input type="checkbox"/> Non-active instruments <input type="checkbox"/> Contraceptive medical devices <input type="checkbox"/> Non-active medical devices for disinfecting, cleaning, rinsing <input type="checkbox"/> Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) <input type="checkbox"/> Non-active medical devices for ingestion <input type="checkbox"/> Non-active medical devices other than specified above <input type="checkbox"/> Other medical devices
Make a brief description of the product and/ or processes of the organization that relate to the desired scope.	
What is the directive applicable to medical devices?	<input type="checkbox"/> Medical Devices Directive <input type="checkbox"/> Directive on in vitro diagnosis <input type="checkbox"/> Active implantable medical devices
What class do your medical devices belong to? If you have more than one type of device, list all products and classifications.	
Are there devices to be placed on the European market?	

What is the purpose of using your device (s)? Please list each device and use for each device separately	
Are your devices sterilized before use?	
If so, does your organization handle this process or a subcontractor?	
Do you have outsourced processes?	
<p>For the appropriate understanding of your requests, for the communication of news related hereto as well as for the continuous notification with regard to other products in our portfolio or marketing campaigns, by the signature of the present document, you agree to our use of personal data related to the employees of your company who come in contact with us, completely in agreement with Regulation (EU) 2016/679. The use of such data may also continue if there is no service agreement signed between the parties, unless you specify your express desire that such data are deleted from our database. For more details on the Personal Data Processing Policy, please visit our website <a href="http://systemaglobal.ro/politica-de-prelucrare-a-datelor-cu-caracter-personal/">http://systemaglobal.ro/politica-de-prelucrare-a-datelor-cu-caracter-personal/</a>.</p>	

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