# **MEDICAL DEVICE QUESTIONNAIRE**

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| Completion Guidance NotesFor SGS to be able to give you an accurate quotation for certification services it is important that we identify the scope of the sites and activities to be audited.Please answer the enclosed questions as fully as possible, if you do not know the answer to a question please type "don't know" and one of our technical team will contact you to discuss.If you have more than one site to be audited, please provide a list of all the site addresses to be included in the scope, and the activities at each site.We may also need to contact you for clarification of your answers so please ensure that you enter your contact details.On receipt of the completed Questionnaire, SGS will prepare and submit a No Obligation proposal detailing the assessment, certification, and other costs, and will be followed up by the local SGS Client Manager.Medical devices regulation (EU) 2017/745 requires that we carry out unannounced audits on all manufacturers, so we ask for information on all your sites and your critical sub-contractors as potential sites where we may need to audit.If you are an existing SGS Fimko client applying for additional certification, please indicate the additions only. For extensions to scope to existing certification please use SGS Fimko Notification forms.For MDR certification, SGS may only provide a contract proposal to the legal manufacturer of the medical device, so the entity that will be taking responsibility for its CE Marking under the MDR.Before applying to SGS Notified Body, manufacturers must register the information in Section 1 of Part A of Annex VI of the MDR to the Commission Electronic Registration System and obtained a single registration number to identify that manufacturer.For MDR certification: MD manufacturers of any Class must have applied for a Basic UDI-DI to apply to that device before the manufacturer applies to SGS Notified Body for conformity assessment under Annex IX.If you have already applied with another notified body and withdrawn your application, please inform us about it and about the reason of refusal in the medical device section below.Please return in electronic format or hard copy to your contact person in the local SGS certification office or directly to NB as shown below:SGS Fimko Oy Takomotie 8 00380 Helsinki  Finland  Phone: +358 9 6963 701  E-mail: nbmed.fimko@sgs.com | | | | | | |
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| **Section 1: Contact Information** | | | | | | |
| Company name (Legal Entity): | |  | | | | |
| If company is part of a group, please specify: | |  | | | | |
| Website: | |  | | | | |
| Company VAT (TVA) Number: | |  | | | | |
| If applicable, e-invoicing address: | |  | | | | |
| Type of Economic Operator: | | Manufacturer | Distributor | | | Importer |
| European Single registration number(s): | |  | | | | |
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| Main Address: | |  | | | | |
| (Certification Address, if different): | |  | | | | |
| (other Address 1): | |  | | | | |
| (other Address 2): | |  | | | | |
| Person completing the questionnaire: | |  | | | | |
| Position: | |  | | | | |
| E-mail: |  | | | Tel N°: |  | |
| Person(s) Responsible of Regulatory Compliance: | |  | | | | |
| Position: | |  | | | | |
| E-mail: |  | | | Tel N°: |  | |
| Primary Contact Person: | |  | | | | |
| Position: | |  | | | | |
| E-mail: |  | | | Tel N°: |  | |
| Secondary Contact Person: | |  | | | | |
| Position: | |  | | | | |
| E-mail: |  | | | Tel N°: |  | |
| Guidance Notes: Please provide a primary contact person who will be the main contact for arranging audits, and in the case of unannounced audits and urgent regulatory queries. The secondary contact person would be the person who will deputise for the primary contact. | | | | | | |

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| **Section 2: The Services you wish to receive from us** | |
| **Certification by the Certification Body SGS Fimko Ltd.** |  |
| **ISO 9001:2015 (FINAS Accredited)** |  |
| **ISO 14001:2015 (FINAS Accredited)** |  |
| **ISO 13485: 2016 (+ EN ISO 13485: 2016) (FINAS Accredited)** |  |
| **Certification by the Notified Body SGS Fimko Ltd. 0598**Regulation (EC) 2017/745 for CE Marking of medical devices *- please choose a conformity route for your certification* (if you’d need more than one route for your products, please indicate the products with differing routes in Section 4) | |
| Annex IX (I) (QMS) |  |
| Annex IX (II) (Technical Documentation Assessment,only for class IIb-Implantable or class III) |  |
| Annex X (Type Examination) |  |
| Annex XI (A) (Production Quality Assurance) |  |
| Annex XI (B) (Product Verification) |  |

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| Have you already/previously applied with another MDR (EU) 2017/745 notified body and your application has been withdrawn by you or refused by the other NB, please inform us about it and about the reasons? *Reasons for withdrawal/refusal:* | Yes |  | No |  |

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| **Certifications by SGS UK Ltd.** Country specific regulations | |
| MDSAP program (if selected, we will send you a separate MDSAP questionnaire) |  |
| UKCA program (if selected, we will send you a separate UKCA questionnaire) |  |
| Other (specify): |  |

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| **Transfers to SGS** | | | | | | | | |
| Do you want to transfer any medical device or quality system certification to SGS? *(If yes, please provide copies of certificates)* | | | | | Yes |  | No |  |
| Reason for transfer to SGS: | *Cost* | *Service* | *Range of certification* | *original body ceased operation* | | *Other (specify):* | | |
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| Transfer timing: | Date of last audit | | Expected date of next audit. | | | | | |
| Transfer from: | *(auditing organization)* | | | | | | | |

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| If you do not see the standard or regulatory scheme you require in the list above, please indicate: |
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| **Section 3: About your Organisation** | | | | | | | | | | | |
| Are your systems integrated? | | | No | |  | Partially | |  | | Fully |  |
| *(By systems we generally mean manufacturing processes, e.g. if you make a finished metal implant do you get the raw material in and work them to the final product [fully integrated] or do you bring in sub-assemblies which are then finished [partially integrated], or do you sub-contract all manufacturing and only bring the finished product on-site to pack and ship [no integration].)* | | | | | | | | | | | |
| Total number of employees in the organisation: | | |  | | | | | | | | |
| Total number of employees in the activities to be certified: | | |  | | | | | | | | |
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| **Activities:** Please list the main processes or activities to be covered by the certification: *(e.g. management, design and development, production, service provision, servicing, measurement analysis and improvement, purchasing, sales, regulatory, vigilance, …)* | | | | | | | | | | | |
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| **Off –site activities**: Do you conduct any activities off-site during daytime working hours? Please give details: | | | | | | | | | | | |
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| **Design**: Do you have design responsibility? | | | | | | | Yes | |  | No |  |
| **Shift system**: If the company operates a shift system, please provide the number of employees per shift, the times of the shifts and a descriptions of the activities per shift: | | | | | | | | | | | |
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| **Locations for Multi-site Certification** [more than one site under the same Quality Management System] | | | | | | | | | | | |
| How many sites will be covered by the certification in total? | | | |  | | | | | | | |
| Please provide the list of site addresses and a brief description of activities and amount of FTE at each site or group of sites: | | | | | | | | | | | |
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| *Please provide a separate table if more than four sites in total.* | | | | | | | | | | | |
| **Scope of Certification** | | | | | | | | | | | |
| If you have a specific scope statement (proposal or existing) for your certifications, then please indicate: | | | | | | | | | | | |
| MDR (EU) 2017/745 |  | | | | | | | | | | |
| ISO 13485 (all versions) |  | | | | | | | | | | |
| ISO 9001 (all versions) |  | | | | | | | | | | |
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| **Additional Information** | | | | | | | | | | | |
| Which other certification / registrations does your company hold (if any)?:  *Please attach copy of certificate(s)* | | | | | | | | | | | |
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| **Consultancy and other services rendered concerning medical devices during last 3 years**  Please check relevant boxes and give further information below in Section “Details” | | | | |
| Consultancy services in the field of medical devices? | Yes |  | No |  |
| Training activities in the field of medical devices? | Yes |  | No |  |
| Internal audits? | Yes |  | No |  |
| Consultancy services as regards EU requirements for the design, construction, marketing or maintenance of the products under assessment | Yes |  | No |  |
| Services related to pre-clinical studies, clinical evaluation, clinical investigations | Yes |  | No |  |
| Laboratory testing services (e.g. testing for electro-medical devices) | Yes |  | No |  |
| Clinical research | Yes |  | No |  |
| Please describe name of organisation / person(s) that are delivering or had delivered services in the field of medical devices for any box that has been check with “Yes”: | | | | |
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| **Section 4: Medical Devices information** | | | | |
| In what language is your device technical documentation? |  | | | |
| In what language are your quality system procedures? |  | | | |
| Do you design software (stand alone or embedded) that is used to control your devices? | Yes |  | No |  |
| Do your devices incorporate Artificial Intelligence components? | Yes |  | No |  |
| Do your devices incorporate non-viable human or animal material or derivatives)? | Yes |  | No |  |
| Do your devices incorporate nanomaterials? | Yes |  | No |  |
| Do your devices incorporate medicinal products, medicinal components (e.g. active silver) or pharmaceuticals? | Yes |  | No |  |
| Do your devices incorporate substances absorbed by or dispersed in human body? | Yes |  | No |  |
| Do you supply implantable devices? | Yes |  | No |  |
| Do you undertake any operations within a controlled environment or cleanroom? | Yes |  | No |  |
| Do you supply devices in a sterile condition? | Yes |  | No |  |
| Do you use a sterilization supplier? | Yes |  | No |  |
| Do you supply implantable devices? | Yes |  | No |  |
| Do you supply devices that are to be sterilized by the end user? | Yes |  | No |  |
| Do you supply devices that are reusable surgical instruments? | Yes |  | No |  |
| Do you supply devices that are having measurement functions? | Yes |  | No |  |
| Do you supply devices without an intended medical purpose (MDR Annex XVI)? | Yes |  | No |  |

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| **In-house or 3rd Party testing for electro-medical devices**: Do you use harmonized standards such as the EN 60601 family for your device to show conformity? Is testing carried out in-house, or in an unaccredited 3rd party test house [no accreditation to ISO 17025] or at a 3rd party accredited test house?  Do you use any other alternative methods instead?  Please give details: |
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| **Sterile devices:** If you operate sterilization processes on site please give details of the types of processes: |
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| **Sterilization subcontractor:** If you use a sterilization sub-contractor please give the name & address of the sub-contractor, the types of processes and details of their certification or approvals: |
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| **OEM:** If other companies subcontract your manufacturing or design services and sell medical devices manufactured or designed by you under their own name and hence take the legal manufacturer’s responsibility, please give details of product ranges and names & addresses of those companies: |
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| **Reusable product:** Please give details of the aspect relating to the reuses of the device: |
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| **Critical Subcontractors and crucial suppliers (including O.E.M. suppliers):** If there are any other outsourced processes critical to the product, please give the sub-contractor names and details of outsourced process or activity (SGS will assume that all your critical sub-contractors and suppliers have appropriate certification or control for the activities they provide for you, and that no additional audit time is needed to assess them. If they do not, please provide brief details how you control them.) |
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| **Other relevant product information** |
| **ISO 13485 certification under MDSAP requirements (AUS, BRA, CAN, JPN, USA)**  **Define the range of products sold or to be sold in MDSAP countries, including the classification of each product** (if MDSAP certification was requested, we will send you a separate MDSAP questionnaire for further details) |
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| **Products to be certified under MDR (EU) 2017/745** | | | | | | |
| Technical File  Name / Number | Device: name, description and intended use | ClassificationClass I (measuring or sterile),Class IIa, IIb | Classification rules | Basic UDI-DI | Suggested MDA/MDNMDS/MDT | Suggested EMDN |
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| **Section 5: Attached documents (e.g. previous/current certificates)** |

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| **Following documents are attached to this Questionnaire** | |
| Name / Number | Description |
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| **Technical Areas within ISO 13485:2016 scope (IAF MD9:2023 Table A1)** Please tick all that are applicable, also if you have not applied for ISO 13485:2016 | | | |
| --- | --- | --- | --- |
| Applicable | ID | Technical Area within ISO 13485:2016. | Product Categories Covered by the Technical Areas |
| 1.1 Non-Active Medical Devices | | | |
|  | 1.1.1 | General non-active, non-implantable medical devices | * Non-active devices for anaesthesia, emergency, and intensive care * Non-active devices for injection, infusion, transfusion, and dialysis * Non-active orthopaedic and rehabilitation devices * Non-active medical devices with measuring function * Non-active ophthalmologic devices * Non-active instruments * Contraceptive medical devices (\*) * Non-active medical devices for disinfecting, cleaning, rinsing * Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) (\*) * Non-active medical devices for ingestion (\*) |
|  | 1.1.2 | Non-active implants | * Non-active cardiovascular implants (\*) * Non-active orthopaedic implants * Non-active functional implants (\*) * Non-active soft tissue implants (\*) |
|  | 1.1.3 | Devices for wound care | * Bandages and wound dressings * Suture material and clamps * Other medical devices for wound care |
|  | 1.1.4 | Non-active dental devices and accessories | * Non-active dental devices/equipment and instruments * Dental materials * Dental implants |
|  | 1.1.5 | Non-active medical devices other than specified above |  |
| 1.2 Active (Non-Implantable) Medical Devices | | | |
|  | 1.2.1 | General active medical devices | * Devices for extra-corporal circulation, infusion and haemopheresis * Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia * Devices for stimulation or inhibition * Active surgical devices (\*) * Active ophthalmologic devices * Active dental devices * Active devices for disinfection and sterilization * Active rehabilitation devices and active prostheses * Active devices for patient positioning and transport * Active devices for in vitro fertilisation (IVF) and assisted   reproductive technologies (ART) (\*)   * Software, including software design for medical devices * Medical gas supply systems and parts thereof |
|  | 1.2.2 | Devices for imaging | * Devices utilizing ionizing radiation * Devices utilizing non-ionizing radiation |
|  | 1.2.3 | Monitoring devices | * Monitoring devices of non-vital physiological parameters * Monitoring devices of vital physiological parameters |
|  | 1.2.4 | Devices for radiation therapy and thermo therapy | * Devices utilising ionizing radiation (\*) * Devices utilising non-ionizing radiation * Devices for hyperthermia / hypothermia * Devices for (extracorporeal) shock-wave therapy (lithotripsy) |
|  | 1.2.5 | Active (non-implantable) medical devices other than specified above |  |
| 1.3 Active Implantable Medical Devices | | | |
|  | 1.3.1 | General active implantable medical devices | * Active implantable medical devices for stimuation / inhibition (\*) * Active implantable medical devices delivering drugs or other substances (\*) * Active implantable medical devices substituting or replacing organ functions (\*) |
|  | 1.3.2 | Implantable medical devices other than specified above | (\*) |
| 1.4 In Vitro Diagnostic Medical Devices | | | |
|  | 1.4.1 | (IVD) Reagents and reagent products, calibrators, and control materials | Clinical Chemistry,  Immunochemistry (Immunology)  Haematology/Haemostasis/Immunohematology  Microbiology  Infectious Immunology  Histology/Cytology  Genetic Testing |
|  | 1.4.2 | IVD Instruments and software |  |
|  | 1.4.3 | IVD medical devices other than specified above |  |
| 1.5 Sterilization Methods | | | |
|  | 1.5.1 | Ethylene oxide gas sterilization (EOG) |  |
|  | 1.5.2 | Moist heat sterilization |  |
|  | 1.5.3 | Aseptic processing |  |
|  | 1.5.4 | Radiation sterilization (e.g. gamma, x-ray, electron beam) |  |
|  | 1.5.5 | Low temperature steam and formaldehyde sterilization |  |
|  | 1.5.6 | Thermic sterilization with dry heat |  |
|  | 1.5.7 | Sterilization with hydrogen peroxide |  |
|  | 1.5.8 | Sterilization method other than specified above |  |
| 1.6 – Devices Incorporating / Utilizing Specific Substances / Technologies | | | |
|  | 1.6.1 | Medical Devices Incorporating medicinal substances |  |
|  | 1.6.2 | Medical devices utilizing tissues of animal origin |  |
|  | 1.6.3 | Medical devices incorporating derivates of human blood | (\*) |
|  | 1.6.4 | Medical devices utilizing micromechanics |  |
|  | 1.6.5 | Medical devices utilizing nanomaterials |  |
|  | 1.6.6 | Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed |  |
|  | 1.6.7 | Medical devices incorporating or utilizing specific substances / technologies / elements, other than specified above |  |
| 1.7 – Parts and Services | | | |
|  | 1.7.1 | Raw materials | Raw metals, plastic, wood, ceramic |
|  | 1.7.2 | Components | Electrical components, fasteners, shaped raw materials, machined raw materials, and molded plastic |
|  | 1.7.3 | Subassemblies | Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions |
|  | 1.7.4 | Calibration services\* | Verification/confirmation services for measuring instruments, tools, or test fixtures |
|  | 1.7.5 | Distribution services | Distributors providing storage and delivery of medical devices, not acting as a ‘legal manufacturer’ for medical devices. |
|  | 1.7.6 | Maintenance services | Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks. |
|  | 1.7.7 | Transportation services | Trucking, shipping, air transportation service in general. |
|  | 1.7.8 | Other services | Consulting services related to medical devices, packaging services, etc. |

Additional questions for suppliers of “Parts and Services”:

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| **We are NOT supplying parts and services and the following questions are NOT applicable** | 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 labelling) | Yes | No |
| Is the product intended to be a component/part of a medical device? | Yes | No |
| Is the organization contracted to carry out any activities that are regulated by a medical device regulation (e.g., relabelling, remanufacturing of other medical devices)? | Yes | No |
| Is the product supplied sterile? | Yes | No |
| Does the product contain software developed by the client organization or a supplier? | Yes | No |
| 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)? | Yes | No |
| Is the product (Raw Materials, Parts, Components, Subassemblies, Maintenance Services, or Other Services) intended to support associated medical devices?  Note: Refer to the note in Annex A, Table A.1.7, a) as an example. | Yes | No |