

**MDR (EU) 2017/745  
EU CERTIFICATION APPLICATION /  
AGREEMENT**

Number: MDR-

**We apply MDR EU Certification according to the Medical Devices Regulation (EU) 2017/745 according to:**

For class III or IIb implantable (except Article 52(4) Paragraph 2) products:

- R3a)  Annex IX (Quality Management System Assessment and Assessment of Technical Documentation sections 4 & 5), OR  
R3b)  Annex X (Type Examination) coupled with Annex XI (Part A: Production Quality Assurance), or  
R3c)  Annex X (Type Examination) coupled with Annex XI (Part B: Product Verification),

For class IIa and IIb (or IIb implantable Article 52(4) Paragraph 2) products:

- R2a)  Annex IX (Quality Management System Assessment and Assessment of Technical Documentation section 4), OR  
R2b)  Annex XI (Part A: Production Quality Assurance) coupled with Annexes II and III,  
R2c)  Annex XI (Part A: Product Verification) coupled with Annexes II and III,

For class I (measuring), I (sterile), I (re-usable surgical):

- R1a)  Annex IX (Quality Management System Assessment\*), OR  
R1b)  Annex XI (Part A: Production Quality Assurance\*) coupled with Annexes II and III  
\* with statement: Audit conducted by SGS Fimko as Notified body 0598 has been limited to the aspect of sterility / measuring functions / reusability properties of the quality management system

For Importers/Distributors:

- R16  Article 16 (Quality Management System Assessment for Cases in which obligations of manufacturers apply to importers, distributors, or other persons)

Based on the selected Annex, the manufacturer commits to supply with the application the documentation and possible samples listed in the Attachment 1 of MDR (EU) 2017/745 EC Certification Application.

**Applicant / Manufacturer:** (Full name of the company, Business ID number)

(Address)

(Contact person, telephone - fax number – E-mail)

**Single Registration Number (SRN):****Invoicing address:** (Contact person, telephone - fax number – E-mail)**Place(s) of manufacture:** (Full name and address of the company)**Authorized representative:** (If manufacturer is not established in the EU. In that case, please attach the agreement between you and the EU REP to the application for review)

Please add below (N/A for Importers/Distributors with R16-only)

- all products (or product series) to be certified,
- all types or models of the product (or types or models within the product series), where applicable,
- risk class of the product based on Annex VIII of MDR, and
- justification rule number from Annex VIII for each product (or type/model, where applicable).
- certification route selected to be used for each device (Article 52, use route numbering as above in this form)

Add lines to this table where necessary.

Product:	Type/Model/Basic UDI-DI:	Risk class:	Justification (rule nr.):	Route:	Schedule to complete the Technical Documentation
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					(either "Ready" or by "YYYY-MM-DD")
<e.g. Electronic Thermometer>	<e.g. models A1, A2, U1234567890>	<e.g. IIa>	<e.g. Rule 10>	<e.g. R2a>	
<e.g. X-ray source>	<e.g. models X1, X2, U1234567891>	<e.g. IIb>	<e.g. Rule 10>	<e.g. R2a>	

**Location for assessment and testing for Annex X Type-Examination:** *(The NB may find reasons to change the place during the assessment due to unavailability of persons or facilities not foreseen before assessment)*

**General information on certification procedures**

The manufacturer/importer/distributor shall fulfil the obligations imposed to the respective role by the Medical Device Regulation (EU) 2017/745 and the conformity procedures of selected Annexes.

Annual surveillance audits and unannounced audits by the Notified Body are required to use the CE marking and Notified Body identification number. The manufacturer/importer/distributor must allow the Notified Body access for inspection purposes to the place of manufacture, inspection, testing and storage and must provide it with all necessary information. In the surveillance audits the Notified Body shall carry out or ask for relevant tests to check that the quality management system is working properly. The Notified Body shall provide the manufacturer/importer/distributor with a surveillance audit report and, if a test has been carried out, with a test report. Device acquisition and testing are performed at manufacturer's expense. Unscheduled, unannounced and short-notice audits may be required at manufacturer's/importer's/distributor's cost in conditions described below. The Notified Body may use subcontractors to perform some of the auditing tasks in-line with MDR (EU) 2017/745 Article 37 and Annex VII requirements.

Unannounced audits of manufacturers, as required in the MDR (EU) 2017/745, shall be performed by the Notified Body at least once every 5 years at manufacturer's expense. The frequency of unannounced audits may be increased if the devices bear a high risk, if the devices of the type in question are frequently non-compliant or if specific information provides reasons to suspect non-conformities of the devices or of their manufacturer. An unannounced audit shall not take less than one day and shall be executed by at least two auditors.

Unannounced audits may be performed at the premises of the manufacturer or at their critical subcontractor or supplier facilities. For countries, where invitation letters or similar are required for travel permits and visas, the manufacturer shall provide such documents with an open date of visit to be filled-in by the Notified Body. The manufacturer shall inform critical subcontractors and suppliers of the possibility of Notified Body audits and ensure that the Notified Body can perform the unannounced audit at their premises. The manufacturer shall provide the Notified Body with an annual manufacturing plan for devices falling under the issued certificate and shall keep the Notified Body informed of changes in the plan.

Where doubts arise as to the conformity of a device, including its documentation, the Notified Body shall carry out or ask for relevant tests of the device. Notified Body shall provide the manufacturer with a test report and with an audit report which highlights in particular the link between quality system deficiencies and detected non-conformities of devices. Device acquisition and testing are performed at manufacturer's expense.

During all audits the manufacturer/importer/distributor shall ensure the safety of the auditors. If the safety of the auditors can be compromised, the Notified Body shall make necessary security arrangements at manufacturer's/importer's/distributor's expense. If the manufacturer/importer/distributor cannot assure permanent, and where applicable unannounced, access to the premises of the manufacturer or its critical subcontractors or suppliers, the Notified Body is authorized to terminate this certification agreement.

The manufacturer must receive a prior approval from the Notified Body to all substantial modifications to the approved type(s) covered by the certificate which might affect conformity with the essential requirements. Notification of the planned changes to the device(s) are done with form FPMREG1008 and the Notified Body will inform of either approval of the change or additional action required prior to the change with the same form. (\*)

The manufacturer/importer/distributor must keep the Notified Body that has approved the quality system informed of any changes of the quality system or regulatory actions that may affect the validity of the current certification or the scope of an audit. Form FPMREG1007 is to be used for notification.

If there are any major non-conformities found in internal or external audits, having a possible effect to the approved type(s) covered by the certificate, the manufacturer/importer/distributor must inform the Notified Body within 14 days.

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The manufacturer/**importer/distributor** will, when translating/having translated the instructions for assembly, use and maintenance, take into account possible national exceptions. The applicant will upon request provide evidence of this.

The manufacturer/**importer/distributor** shall undertake to fulfil the obligations imposed by the approved quality system.

The manufacturer/**importer/distributor** shall undertake to keep the approved quality system adequate and efficacious.

The manufacturer shall institute and keep up to date a systematic procedure to review experience from devices in the post-production phase, including the provisions referred to in Annex XIV, and to implement appropriate means to apply any necessary corrective action.

The manufacturer shall notify the competent authorities and the notified body of incidents 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, and incidents leading to systematic recall of devices of the same type immediately on learning of them. Also, if the manufacturer has doubts of the compliance to MDR of any of the certified products, they must be informed to SFS Fimko. Form FPMDREG2003 is to be used for reporting of EC Vigilance and of any doubts to SGS Fimko.

Modifications, updates or changes in manufacturer's products or **manufacturer's or importer's/distributor's** quality system as well as negative post-market surveillance data, other significant safety related information, justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements may trigger the need for an unscheduled, unannounced or short-notice audit regardless of how this information has come into the Notified Body's knowledge.

Changes to the Type-Examination approved device including limitations of its intended purpose and conditions of use shall require a prior approval from the Notified Body. The Notified Body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the EU type-examination certificate. Changes to the intended purpose and conditions of use of the approved device, with the exception of limitations of the intended purpose and conditions of use, shall necessitate a new application for a conformity assessment by Type-Examination. (\*\* this is partly redundant to section marked \*)

The manufacturer gives the notified body permission to retain all technical file materials. The material will be archived confidential and access to it shall be only by the notified body personnel and when there is a legal justification, by authorities in supervision of notified body personnel.

If the EC certification is supported by QMS certificates issued by other certification bodies, the manufacturer/**importer/distributor** will give SGS personnel full access to the related audit material and will notify SGS of any changes in the said certification.

With this application, the manufacturer/**importer/distributor** (certificate holder) declare(s) that a certificate of conformity has not been applied for or rejected by any other conformity assessment body for the specified products.

The manufacturer/**importer/distributor** understands that the Notified Body

- will inform other Notified Bodies through Eudamed of the manufacturer that withdraws its application prior to the Notified Body's decision regarding the conformity assessment.
- may decide to terminate the certification process and notify of the decision to other Notified Bodies through Eudamed if the certification process has been going on over 18 months from the last date of initial audit and the manufacturer/**importer/distributor** has not been able to correct all the identified major nonconformities during that time.
- may decide to suspend, **restrict** or withdraw the issued certificate and publish the decision in Eudamed
  - o if the manufacturer/**importer/distributor** does not enable the Notified Body to perform its surveillance responsibilities or
  - o if the manufacturer/**importer/distributor** is not able to correct all the identified major nonconformities in due time
  - o if the Notified Body identifies a nonconformity that presents a danger to the users or patients.

The application procedure is based on the currently valid SGS Fimko Codes of Practice.

The manufacturer/**importer/distributor** commits to comply with SGS General Conditions for Certification Services and General Conditions of Service.

This agreement, when signed by the manufacturer/**importer/distributor**, is

- o a written declaration that the name and address of manufacturer/**importer/distributor** and any additional manufacturing site covered by the quality system are specified in this agreement,
- o a written declaration of manufacturer/**importer/distributor** that the Notified Body 0598 (SGS Fimko) is provided with all the relevant information on the product or product category covered by the procedure,
- o a written declaration that the documentation on the quality system is available for the Notified Body 0598 (SGS Fimko).
- o a written declaration by manufacturer/**importer/distributor** that none of the medical devices, unless expressly described in this proposal, contains a component / element:

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- that has or may have a possible pharmacological, immunological, metabolic or antimicrobial activity (according to European Regulation (EU) 2017/745 + amendments)
- that contains animal tissue or derivatives thereof (according to European Directive 2003/32/EC)
- that contains phthalate (according to European Directive 67/548/EEC)
- that contains human cells, blood, tissue or derivatives thereof (according to European Directive 2000/70/EC)
- that contains nanomaterials (e.g. nano-hydroxyapatite, nano-silver) or may generate nanosized particles (e.g. due to wear-and-tear)
- a written declaration by manufacturer/importer/distributor that
  - the technical documentation, which is available for assessment by the Notified Body, either contains or identifies documents defining all the quality management system requirements and that thus no process related to the certified medical devices (design, manufacture, purchase, inspections, ...) is kept hidden or secret from the Notified Body. This is valid both for manufacturer as for the critical subcontractors or crucial suppliers.
  - the technical documentation, which is available for assessment by the Notified Body, either contains or identifies documents defining the full product specifications (composition and components list, both quantitatively and qualitatively) and that thus no product specifications of the certified medical devices are kept hidden or secret from the Notified Body. This concern both purchased as self-fabricated parts / components.
  - the manufacturer/importer/distributor has not received any consultancy services among medical devices from SGS Fimko Oy or any other organization belonging to SGS Group. General training activities that are not client specific and that relate to regulation of devices or to related standards are not considered as consultation and are allowed.
- [only if annex XI of the MDR as the conformity assessment route is chosen for class IIb products] a written declaration that, where appropriate, the technical documentation on the types approved and a copy of the EU type-examination certificates is available to the Notified Body
- an undertaking by manufacturer/importer/distributor to fulfil the obligations imposed by the quality system approved,
- an undertaking by manufacturer/importer/distributor to keep the approved quality system adequate and efficacious,
- an undertaking by manufacturer/importer/distributor to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex XIV of the MDR and to implement appropriate means to apply any necessary corrective action. This undertaking includes an obligation for manufacturer/importer/distributor to notify the competent authorities and manufacturer/importer to notify the Notified Body 0598 (SGS Fimko) of the following incidents immediately on learning of them:
  - 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 the previous subparagraph to systematic recall of devices of the same type by the manufacturer.
- agreement of NB to carry out the type-testing assessments and tests in proposed locations (if applicable) or
- an undertaking by the manufacturer to agree with the Notified Body during the type-testing assessment of possible change of the place (if applicable).
- an undertaking by the manufacturer/importer/distributor to inform the notified body of any changes to the approved type and
- an undertaking by the manufacturer to make a new application for Type-Examination conformity assessment in case of changes to intended purpose and conditions of use the approved device.
- a permission of the manufacturer/importer/distributor to receive communications from the Notified Body to the designated contact persons. If there are changes in the contact persons or contact information, the manufacturer must inform the Notified Body accordingly.

As a result of article 33 and 34 of the MDR, next data cannot be treated by the Notified Body as confidential data:

- (a) data relating to registration of manufacturers/importers/distributors and authorized representatives and devices in accordance with Article 33 and 34 of the MDR excluding data related to custom-made devices;
- (b) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures, as laid down in Annexes IX to XI of the MDR;
- (c) data obtained in accordance with the vigilance procedure as defined in Article 87 to 92 of the MDR;
- (d) data relating to clinical investigations referred to in Articles 62 to 82 of the MDR

SGS Finland shall ensure that confidentiality of the information which comes into its possession during the performance of the conformity assessment activities is observed by its personnel, committees, subsidiaries, subcontractors, or any associated body, except when disclosure is required by law.



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I declare that the application has not been lodged with any other Notified Body.

I declare that the applicant (manufacturer/**importer/distributor**) has not received consultation related to the target of the applied certification from a company belonging to the SGS Group. Third party testing or general training are not regarded as consultation.

Unless otherwise agreed the certificate is issued in English language.

Complaint to the EU Certification decision according to the Medical Devices Regulation (EU) 2017/745 can be made according to the SGS Fimko Ltd's Appeals process within 30 days of the decision date. Please either prepare a free form appeal or use the Appeals form GS0601FI describing why you consider the decision to be incorrect and email it to [nbmed.fimko@sgs.com](mailto:nbmed.fimko@sgs.com).

By signature of manufacturer/**importer/distributor** and notified body SGS Fimko Ltd no. 0598, this application forms an agreement between both parties.

**MANUFACTURER**

\_\_\_\_\_  
*Place and date*

\_\_\_\_\_  
Signatory's name in printed letters

\_\_\_\_\_  
*Legally binding signature of the  
manufacturer/importer/distributor (certificate holder) or  
its authorized representative*

**SGS FIMKO LTD**

\_\_\_\_\_  
*Place and date*

\_\_\_\_\_  
Signatory's name in printed letters

\_\_\_\_\_  
*Legally binding signature of the notified body  
representative.*

**This agreement has been made two similar copies, one for each party.**

In case a translation has been made of this English version of the agreement and there are contradictions, the English version is valid.

This agreement replaces the previous agreement, number MDR-\_\_\_\_ - \_\_\_, dated YYYY-MM-DD