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Project 24Q03053 Rev.01

Subject: EC Certification activity in accordance with Reg. (EU) 2017/745 – Annex IX for the following Medical Devices (MD):

1) **Absorbable Polyglycolic acid Surgical Suture**
2) **Absorbable Polyglactin Surgical Suture**
3) **Non Absorbable Surgical Nylon Suture**
4) **Non Absorbable Silk Surgical Suture**
5) **Non Absorbable Surgical Polyester Suture**
6) **Non Absorbable Surgical Polypropylene Suture**

In response to your kind request and based on previous agreements, we are pleased to confirm our availability to provide the above specified activities as herewith specified.

To accept our proposal, please return this form stamped and signed via fax at +39.011.22.22.226 or by email Epti@cpt.eurofinseu.com

For any clarification, don't hesitate to contact our Customer Service (Tel. +39.011.22.22.225).
Best regards

Eurofins Product Testing Italy Srl
Customer Service Manager
Stefano Compalati

Digitally signed by Potinga Stela
Date: 2025.05.15 16:29:34 EEST
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I. MEDICAL DEVICES UNDER CERTIFICATION and SITES INVOLVED

- Medical Devices under certification:

Medical Device (MD)	MDA MDN	MDS	MDT	Cert. Req.	Class MDR	Legacy Device	Ref. MD
Absorbable Polyglycolic acid Surgical Suture - is a synthetic absorbable, braided, coated suture composed of a Polyglycolic acid (PGA) and is available dyed with or without needle.	1104	1005 1008	2001, 2002 2008, 2011	First cert	III	YES (*)	1)
Absorbable Polyglactin Surgical Suture - is a synthetic absorbable, multifilament, braided surgical suture which is supplied sterile, surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide. Surgical Suture are coated with copolymer of poly(glycolide-co-Llactide)(30/70) and calcium stearate. Absorbable Polyglactin Surgical Suture is available dyed with or without needle.	1104	1005 1008	2001, 2002 2008, 2011	First cert	III	YES (*)	2)
Non Absorbable Surgical Nylon Suture - The proposed device is a nonabsorbable monofilament surgical suture which is supplied sterile. The proposed device will be offered in diameters ranging from USP size 11-0 through 4 and available with or without needles attached. The proposed device is dyed blue.	1104	1005	2001, 2002 2008, 2011	First cert	IIb	YES (*)	3)
Non Absorbable Silk Surgical Suture - Non absorbable Surgical silk Suture is a non absorbable, braided surgical suture which is supplied sterile,surgical suture composed of an organic protein called fibroin.this protein is derived from the domesticated species Bombyx mori of the family Bombycidae.Silk for braided material is processed to remove the natural waxes and gums.Silk suture is dyed black(Logwood extract) and coated with silicone.	1104	1005	2001, 2002 2008, 2011	First cert	IIb	YES (*)	4)
Non Absorbable Surgical Polyester Suture - The proposed device is a coated,braided,non absorbable synthetic surgical suture composed of polyethylene terephthalate which is supplied sterile.The suture is coated with bees wax and dyed green. The color additive is D&C Green 6.	1104	1005	2001, 2002 2008, 2011	First cert	IIb	YES (*)	5)
Non Absorbable Surgical Polypropylene Suture - Non Absorbable Surgical Polypropylene Suture is a nonabsorbable monofilament surgical suture which is supplied sterile. The proposed device is dyed blue. The color additive is [phtalocyaninato(2-)] copper(Color Index Number 74160), and the weight percentage for the color additive is less than 0.1%.	1104	1005	2001, 2002 2008, 2011	First cert	IIb	YES (*)	6)
(*) MD for which the tripartite agreement (including the MDD NB) is required in case of MDD Surveillance takeover before 26/09/2024.							
Note: during the Application Review phase and/or during the certification process we will carry out the check of the codes and classifications actually applicable to the devices. In the event the codes and classifications above would result as not corrected, we will terminate the present quotation/contract and, where possible (codes and classifications falling into our scope), we will issue a new quotation							

- Sites / Plants involved and to be audited by the Inspectors:

COMPANY	FUNCTION / PROCESS MANAGED	FTE N°	Ref. MD	AREA (*)	Ref. Site
Shandong Haidike Medical Products Co., Ltd. - Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China	Manufacturer: legal site, production, packaging, warehouse, sterilization	60	All	MDR/MDD	A)
(*) Sites marked only with Area MDR will be subject to Audit on the basis of the evolution of the phases of the MDR certification process. Sites marked only with Area MDD will be subject to Audits only to maintain the validity of MDD certified products pursuant to Regulation (EU) 2023/607. Sites marked Area MDR/MDD will be audited both to maintain the validity of the MDD certificates and during the activities envisaged for the MDR certification.					
Note: in the event that during the Application Review phase and/or during the certification process our Experts and Inspectors should find that other sites additional to the ones above have to be audited (Eg. because there some critical processes are managed in full or partially, same sites will have to be audited in order to move forward with the process and related invoicing will occur by basing on tariffs shown in Par. III.V and actual commitments (audit time, travel time, travel expenses)					

IIa. METHODOLOGY – MDR CERTIFICATION

The activity provides the following steps:

- Acceptance of the quote:
  - in order to accept the present quotation you are required to send it stamped and signed by your legal representative in both dedicated sections for signature at the bottom together with the information sheet table filled;

- you are also required to send your formal Request for Certification filled, stamped and signed by your legal representative on your company letterhead (form attached), in accordance with Par. 4.3 of MDR – Annex VI, and jointly with the documents listed here below.

Note: the start of the activities and, in particular, the opening of the process and the execution of the Application Review does not imply definitive acceptance of your application, nor the stipulation of the Certification Contract, which will be evaluated and possibly definitively confirmed only following a positive outcome of the Application Review.

- Documentation required - Preliminary phase: in order to be able to carry out the preliminary activities for the definitive stipulation of the Certification Contract you will have to send us the necessary documentation (in Italian or English) for the execution of the Application Review as required by Reg. (EU) 2017/ 745 - Annex IX - Chapter I - point 2.1 and Chapter II - point 4.1. In summary, a copy of your QMS, some documents of the technical file, the description and classification of the MD and, for class IIb Implantable and III MDs, the complete technical file.

- Application review: having received the above documentation, we will proceed with the analysis of the same with reference to point 4.3, third paragraph of Annex VII of the MDR.

- Order Confirmation: following the successful Application Review, we will proceed to send the Order Confirmation which will constitute the formal stipulation of the certification contract also pursuant to point 4.3, second paragraph of Annex VII of the MDR.

- Documentation required - Activation of the certification procedure: to start the certification activities, the submission of the complete Technical File of each device (in Italian or English) is required, having already acquired the documentation of the Quality Management System.

- Examination of the technical documentation: We will then proceed with the verification of the conformity of the Technical File according to Annex IX, chapter II and chapter III and the drafting of the relative Documentary Examination Report for each product evaluated, with an indication of any deficiencies found and any need to carry out examinations, tests and checks. We will also proceed with the verification of the assessment of clinical efficacy and the relative release of the Report.

- Additional activities that may be required where applicable: with reference to:
  - Medical devices incorporating medicinal substances;
  - Medical devices manufactured utilising tissues or cells of animal origin, or their derivatives (falling into Reg. EU No. 722/2012;
  - Medical devices composed of substances or a combination of substances to be introduced into the human body via a body orifice or the dermal route and that are absorbed by or locally dispersed in the human body, according to applicable provision of the Directive 2001/83/EC – Annex I;
  - Medical devices, or their metabolism products, which are systematically absorbed by the body in order to achieve their intended use;
  - Class III implantable medical devices and class IIb active devices intended to administer and / or remove a medicinal product from the body;

  where applicable, the Verification of the clinical data, the Verification by specialized and qualified professionals in the sector, the opinion and / or approval by competent European Agencies and Commissions, the Preliminary Verification of the Reports to be submitted to the same Agencies and Commissions, are necessary as specified below in the economic conditions.

- Initial certification Audit: it will be conducted at the Manufacturer site, at the production site and at all the sites involved in the critical processes of the production and marketing of the devices (including critical suppliers). During the Audit an examination of the QMS will be conducted with the consequent release of a Report.

- Certificate release: in case of positive outcome of all the activities above, we will issue the Certificate according to Reg. (EU) 2017/745 – Annex IX with a validity as specified in Chp. IV of the present quote.

- Surveillance activity – Audits: Surveillance Audits will be carried out during the duration of the assignment to maintain the validity of the certification of your production, in order to verify the correct functioning of the quality system, the conformity of the product and monitor any changes made to the Technical Files. These audits will take place on an annual basis (as further detailed in Chapter III), will be scheduled well in advance of the deadlines and, at the end of each Surveillance, a specific Inspection Verification Report will be issued. For Medical Devices Class III, tests on materials and essential parts of the device from which the integrity of the same depends on, will be conducted during the Surveillance Audits. For class III MDs, sampling will be carried out in the Surveillance Audit in order to have tests carried out on the essential materials/parts on which the integrity of the MD depends

- Unannounced / Short Notice Audits: they have to be conducted at least one time every 5 years and with the purpose of checking the correct functioning of the QMS and the conformity of the devices. During these Audits, samples of the medical devices under certification might be picked from the production and sent to laboratory for testing. Outcome of the Audits will be a Report including reporting of the laboratory testing where conducted.

- Note - Examination, tests and verifications: the need of these activities may arise from the Technical File assessment and Audits. They will be quoted separately with specific quotations for the purpose.
- Note - Audit planning: the planning of the Audits with reference to information shown on Chapter I of the present quotation may change during the validity period of the certification depending on the following factors: the size of the organization, the scope and complexity of the management system, the products and processes, the level of effectiveness demonstrated by the management system, the results of previous audits, inadequate control over suppliers and crucial suppliers.

IIb. METHODOLOGY – MDD SURVEILLANCE

With reference to **Legacy Devices** (devices already certified pursuant to Directive 93/42/EEC - MDD), for which it will be required and it will be possible to enter into an agreement with Eurofins Product Testing Italy for certification according to Reg. (EU) 2017/745 MDR , we are expected to take charge of the Surveillance of the Certification according to Directive 93/42/EEC MDD (issued by us or another Notified Body) in any case and no later than **26 September 2024**, in accordance with what is indicated in point 1) of the Reg. (EU) 2023/607, which modifies the art. 120 (3) of Reg. (EU) 2017/745.

The activity provides the following steps:

- Documentation required - Preliminary phase: for the purposes of extending the MDD Certificate, pursuant to Regulation (EU) 2023/607 it is necessary that you send us, by and no later than **26 May 2024**, the provisions of the aforementioned Regulation and the explanatory document of the European Commission "Extension of the MDR transitional period and removal of the 'sell off' periods" – Q&A p.to 8. In particular, you must send us:
  - the description and classification of the Medical Device(s) according to the MDR;
  - the Manufacturer's Declaration (fac-simile will be sent);
  - the presentation plan of the technical files;
  - copy of the Quality System updated to what is required by Reg. (EU) 2017/745 and already adopted in the company.

  Furthermore, for devices MDD certified not by our Notified Body:
  - copy of the CE certificates according to MDD issued by the previous Notified Body;
  - copy of the audit reports issued by the previous Notified Body for the entire last certification cycle. Where NCs have been managed in the last audit received from the previous Body, a copy of the resolutions and acceptance by the previous ON (if present) is required;
  - complete copy of the current version of the Technical File approved by the previous Notified Body, in order to access the information necessary for carrying out the surveillance activities. Note: Responsibility for product conformity assessment remains with the former Notified Body;
  - full copy of the assessment reports of the changes made to the technical documentation in accordance with Art120 MDR and MDCG 2020-3 and approved by the previous Notified Body. Subsequent changes to this agreement will be evaluated by Eurofins Product Testing Italy S.r.l. in accordance with the provisions of Art.120 of the Medical Regulations and the MDCG 2020-3 guideline.

  NOTE: In order to be able to take charge of MDD Surveillance, it is necessary to have already stipulated a Contract for the MDR certification of the same Devices

- Check of the documentation: together with the MDR Application Review phase, if not yet carried out, we will proceed with the analysis of the documentation requested above and sent by you with any request for integration of information and documentation that may be missing. Following a positive outcome of the verification, we will proceed with the possible acceptance of your request by sending the Order Confirmation and consequent signing of the final agreement, **which cannot take place beyond 26 September 2024**.
  NOTE: where it is required to take charge of the MDD Surveillance prior to 09/26/2024, it is necessary to stipulate the Agreement between the Manufacturer, Eurofins Product Testing Italy and the outgoing Notified Body as provided for in point 1) of Reg. (EU) 2023/607 which updates art. 120.3 sexies of Reg. (EU) 2017/745.
- Surveillance Audits: we will then proceed with the first Surveillance Audit and, subsequently, with the subsequent ones which must be carried out approximately every 12 months (without prejudice to our possibility of bringing them forward if deemed necessary and appropriate). At the end of each Surveillance Audit, a specific Inspection Verification Report will be issued.
- Un-expected Audits: one must be carried out at least every three years aimed at verifying the correct functioning of the quality system and the conformity of the product. During these visits, samples of the certified products may be taken in order to carry out laboratory tests. At the end of the Audit, a Verification Report will be issued and, if tests have been carried out, a test report.
- Examinations, tests and verifications: where necessary, any examinations, tests and verifications will be carried out, and will be quoted to you separately. This need can arise from un-expected audits or any other check.