Guide for STANDARD 100 by OEKO-TEX®

1. **Application**

Before sending the filled in application to RISE IVF AB, please make sure that the following is performed and/or enclosed.
If you are applying for textile articles you can ignore all questions regarding leather and vice versa.

1.1 **Application form, pay special attention to the following.**

- Clause 1 in the Application, description of the products to be certified, including composition and accessories, (proposed certificate scope / renewal, changes at if any / extensions, changes).
- Clause 5 in the Application, name of person responsible for the quality assurance
- Page 19 in the Application form or a separate enclosed list, suppliers of certified source materials (also see clause 1.4 below).
- Page 20 in the Application form or a separate enclosed list, suppliers of not certified source material (also see clause 1.5 below)
- The Application is dated and signed
- Clause 7.6 anf 7.7. Answer yes if you use substances with biological or flame retardant properties and refer to the name of the product. Answer no if you don’t.
If your supplier use substances with biological or flame retardant properties, answer no and refer to the name of the product or the suppliers certificate.

1.2 **Attachments enclosed, i.e.**

- Copies of supplier’s certificate.
- A list of all certified materials in stock that was produced and delivered during the period of the suppliers now expired certificate.
- Copy of the certificate if an external certified management system is applied, clause 5.1 in the Application
- A short description of the quality system (if an “In-house system” is applied), clause 5.1 in the Application, also see clause 1.3 below.
- A sample of each uncertified material.
  (min 100 g/material for the chemical tests / (min (30x30) cm for colour fastness tests)
- Reference samples (certified ingoing material). According to clause 6.1 in the Application form.
- Clause 4.3. If the address of own production site(s), storage site(s) is different from the address stated on page 4, or if subcontractors are used, list addresses separately and attach enclosure.
- When your supplier is not the certificate holder, a proven link between the supplier and the certificate holder should be shown. This could for example be copies of invoices (from certificate holder to supplier), delivery papers, pictures of source material or packaging if labeled with certificate holders licensnumber or a letter of commitment from the certificate holder declaring that the supplied articles are covered by valid certificates.
1.3 Description of an in-house quality system shall include the following:

- Certified suppliers: Who is choosing suppliers and how do you verify that the material you buy are covered by the suppliers certificate?
- Not certified suppliers, if any: Who is choosing suppliers and what kind of agreement do you have with suppliers without certificate?
- How is the incoming purchased materials handled and verified?
- How is the production secured regarding that correct ingoing materials are used? Production orders (what kind of information does it contain) or other ways?
- If outsourced processes are used, how are these secured; what kind of agreement do you have with the subcontractor?
- How is produced articles handled, controlled and verified?
- The relationship with the customers; how do you/will you communicate about your certificate with the buyers of the articles.

1.4 Suppliers list of certified source materials shall include the following:

Page 19 in the Application form or a separate list.

- Supplier is the invoicing company. If the supplier is not the same as the certificate holder, state both names, supplier and certificate holder.
- State exactly what is bought from each supplier, i.e. composition, (fiber, yarn, fabric, product), (raw, dyed, printed), if treated with any finishing i.e. flame retardant etc.
- Certificate number, expiry date, class and if certified according to annex 4 or 6.

1.5 Suppliers list of non certified source materials shall include the following:

Page 20 in the Application form or a separate list

- Supplier is the invoicing company. If the supplier is not the same as the producer, state both names, supplier and producer.
- State exactly what is bought from each supplier, i.e. composition, (fiber, yarn, fabric, product), (raw, dyed, printed), if treated with any finishing i.e. flame retardant etc.

2. How to work with suppliers with STANDARD 100 by OEKO-TEX® certified source material

Do not forget that every certificate holder is responsible for their own certified products. Your suppliers are responsible for their products and when you sell your certified products, you are responsible for that your products fulfil the requirements in STANDARD 100 by OEKO-TEX®. When you intend to buy STANDARD 100 by OEKO-TEX® certified source material always read the certificate scope very carefully.
2.1 Suppliers with STANDARD 100 by OEKO-TEX certified source material.
- Is the article with the fibre composition that you will buy included in the certificate even if the description is consistent? Not all producers certify all their manufactured products and sometimes certain articles are excluded from the certificate because of failed tests.
- Is the certificate valid for raw material or for dyed and finished
- If the certificate is valid for commission work – where does the source material come from?
- Is the certificate issued in (at least) the same product class as the one you apply for?
- Look at the expiry date to make sure that the certificate is valid. A validity check of a certificate number can be made at www.oeko-tex.com/validity. Make sure that the certificate is valid when your articles are produced.

2.2 Manipulated copies
Manipulated copies of certificates are not valid. Do not accept copies where any part of the text has been left out or changed.

2.3 Suppliers Agreement with suppliers having a STANDARD 100 by OEKO-TEX certificate.
We recommend to set up a written agreement between your company and the suppliers. The written and signed agreement shall ensure that the supplier inform your company regarding any changes of their certificate, i.e.
- The supplier will inform your company if the supplier decides not to renew their certificate before the end of the validity period.
- The supplier will inform your company if there are any changes of the scope of their certificate which affects the items you purchase.
- The supplier will pay the costs if tests are necessary due to a delay of renewal of their certificate.

2.4. Ongoing control
Please do not forget to continuously check the validity of the certificate of your suppliers so that you make sure that your source material corresponds to STANDARD 100 by OEKO-TEX® through the whole period of validity of your own certificate.

2.5. Information obligations
You are obliged to inform RISE IVF AB about changes.
If you change supplier, please send information immediately about the new supplier with a copy of the certificate and reference material
This is also valid for not certified source material, but in this case we will also need to test the material to verify that the requirements are fulfilled before it’s taken in use.
3. **On Site Visit**

As a part of the certification process according to STANDARD 100 by OEKO-TEX®, On Site Visits must be performed. Before issuing the first certificate or within 6 months from the issuing date, thereafter each third year. The On Site Visit consist of both an office meeting and a production tour. After the On Site Visit you will receive a report with including our general impression and the findings we might have found. Findings are divided in recommendations and obligations. Obligations must be fixed within the agreed date.

3.1 **Main purpose of On Site Visit**

- Verify that information given in the Application form is correct.
- Ensure correct communication regarding certified articles to clients.
- Check and verify the traceability and use of materials/articles/dyes and chemicals.
- Verify the stated quality system.

3.2 **Prepare yourself for the On Site Visit**

- Have your OEKO-TEX® application document available.
- Prepare a list of all production sites, own and subcontractors.
  The list shall include: company name, address/country and what service they are contracted for.
- Prepare to guide us through production and storage areas.
- Be prepare to be able to show document such as i.e. suppliers invoices, production orders etc.
- Prepare to show how you communicate your certificate to your clients, webpage, labeling on product, brochures etc.
- Be prepared to show test reports, own and or from external labs as well as documentation from control of incoming goods and control of final goods.

4. **Useful information**

- There are 3 different kind of suppliers
  1. Direct suppliers – Supplier with valid certificate in his own name.
  2. Indirect supplier - Supplier without certificate providing valid certificate of his supplier.
  3. Non certified supplier - Supplier providing materials without valid certificate
- Materials from Indirect suppliers might be spot-checked during the certification procedure.
  The test cost is invoiced the applying company.