elis CLEANROOM

CLEANROOM SOCKS

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Introduction

A cleanroom is a controlled environment that has a low level of contamination such as particles and microorganisms. Cleanrooms are used in a variety of settings, including hospitals, pharmaceutical companies, life-sciences, bio-sciences, and electronics manufacturing plants. In these settings, a cleanroom is necessary to prevent contamination that could affect the quality or purity of the products that are being produced. The goal of a cleanroom is to protect a product or patient from any form of contamination. The level of cleanliness is determined per classification according to the ISO 14644.
In that matter, they are classified by the number of particles per cubic meter at a specified particle size. The higher the class, the cleaner the room. This must be maintained in a certain chain of contamination control (3C-model). In this chain of contamination control, there are multiple aspects important to determine the total strongness, which are:

- Classification (temperature, humidity, pressure)
- Cleaning and its regime
- Operations (working activity)
- Operator's behaviour
- Gowning regime

In the new revised GMP Annex 1 there are some new highlights on several aspects within gowning, such as wearing goggles in A/B environments, dedicated undergarments, but also dedicated cleanroom socks. Many companies with cleanroom facilities let their operators wear usual street socks, which are basically home worn socks made of cotton and full of particles and bacteria, not to mention the actual particle shedding by the material itself. This could lead to harmful situations inside the cleanroom, not supportive in protecting the product.

Therefore, this legislation have put the following on socks:

> 7.14 Cleanroom gowning should be performed in change rooms of an appropriate cleanliness grade to ensure gown cleanliness is maintained.
> Outdoor clothing including socks (other than personal underwear) should not be brought into changing rooms leading directly to grade B and C areas. Single or two-piece facility trouser suits, covering the full length of the arms and the legs, and facility socks covering the feet, should be worn before entry to change rooms for grades B and C.
> Facility suits and socks should not present a risk of contamination to the gowning area or processes.
>
> *Source: new revised Annex 1 2022*

It does not state specifically of where the socks should be made of, but it states that it should not be a risk due to particle shedding towards the cleanroom environment. I t needs to be facility owned socks and other than personal underwear.
What are cleanroom socks and which options do you have to choose from?

Cleanroom undergarments

Cleanroom socks are socks that are specifically designed for use in cleanrooms. T hey are made from materials that are suitable for use in cleanroom environments, such as polyester, nylon, or polypropylene. These materials are chosen because they are low-linting and non-shedding, which means they do not produce particles that could contaminate the cleanroom.

Cleanroom socks are typically worn to eliminate personal socks, usually made of cotton, from critical environments as they would generate particles inside a cleanroom environment.

Cleanroom socks would act as pre-filter, whereas a (sterile) boot, usually worn in higher classification cleanrooms, act as head filter. They are commonly worn in pharmaceutical manufacturing plants, semiconductor manufacturing plants, and other settings where cleanliness is critical.

example of fabric factory

Technical info explained

It is important, before making a decision on cleanroom socks, what all technical info means which is been shared on a technical datasheet. If you test a sock and you gained negative feedback, after reading this section, you will be able to compare the feedback with the technical details and based on your technical knowledge you can search for the right cleanroom sock.

To fully comprehend, an example is been given of technical details regarding a cleanroom sock.

- Main yarn: 150 Den / 288 filament; 100% Polyester
- Back yarn: 70/20 Polyester / Elastane
- 140/140 Polyamide / Elastane

When knitting there are two threads that are pulled through the same needle, i.e. : the main yarn or front yarn and the back yarn. The main yarn in this case is the Polyester thread. The back yarn is the Polyester / Elastane thread that must ensure the elasticity of the sock. 70/20 is referring to the thickness of the yarn. 140/140 is the sewing thread that is added to make the cuff of the socks.

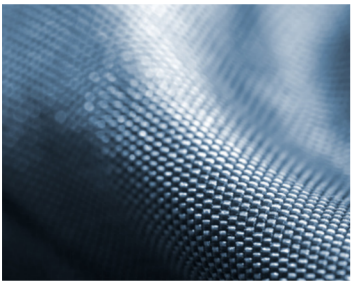
Denier is the weight of 9,000 m of yarn and Dtex is the weight of 10,000 mm of yarn, meaning that you could calculate from Denier to Dtex by dividing, in this case 150 by 0,9 times 1, to see that 150 Denier is 167 Dtex. The lower the value of denier, the finer the yarns are and the more transparent the cleanroom socks becomes.

Synthetic yarns are made by a machine by compressing yarns together. The way they are compressed determines how they will look (smooth, shiny, etc.). It is a composite yarn consisting of a number of filaments, which may or may not be twisted next to each other. The more filaments present, the thicker the cleanroom sock will be. In this case, for 150 Den, the following filaments are available; 36, 48, 96, 144, 288 filament.
It means that this sock is a quite thick sock.

What is polyester?

Polyester is a synthetic polymer made from the combination of a dicarboxylic acid and a dihydric alcohol. It is a strong and durable synthetic fiber that is resistant to shrinkage, wrinkling, and fading. Polyester is often used in the production of clothing, upholstery, and home furnishings, as well as in the manufacturing of various industrial products.
One of the main benefits of polyester is its strength and durability. It is resistant to most chemicals, shrinking, and wrinkling, making it a popular choice for use in a variety of applications. Polyester is also easy to care for, as it is resistant to shrinking and fading when washed and dried.
It is a lightweight and breathable material that is easy to transport and handle, making it a popular choice in the manufacturing industry.

What is nylon (polyamide)?



Nylon is a synthetic polymer made from the monomers diamine and diacid chloride.
It is a strong, durable, and lightweight synthetic material that is widely used in a variety of applications, including clothing, rope, and automotive parts. Nylon is known for its strength and durability, as well as its resistance to abrasion, wear, and tear. It is also resistant to many chemicals and has a high melting point, making it ideal for use in a wide range of temperature-sensitive applications.

Nylon is a flexible material that can be easily moulded into a variety of shapes and sizes, making it a popular choice in the manufacturing industry. It is also a lightweight and breathable material that is easy to transport and handle.

What is polypropylene?

Polypropylene (PP) is a thermoplastic polymer that is known for its strength, flexibility, and durability. It is resistant to many chemicals and has a high melting point, making it ideal for use in a wide range of temperature-sensitive applications. Polypropylene is also non-toxic and can be easily moulded into a variety of shapes and sizes. It is a lightweight material that is easy to handle, and thus making it a popular choice in the manufacturing industry. There are also possibilities of making these type of yarns antibacterial by using silver ions into the yarns.

What is elastane?

Lycra, spandex and elastane are the same material. These are elastic or stretchable yarns. Often added to a yarn in a sock for increasing comfortability.

What to choose?

In this world of all different yarns and blends of so many flavors, it is difficult to determine which flavor would suit you. Of course, it depends on what you and your company find important. To give you some guidance, there are several aspects to consider one sock over the other, such as:

Material

- First of all, only fibers that are non-linting and not shedding particles for cleanroom environments.
- Polyamide and polyester are synthetic fibers. Polypropylene is more natural, more sustainable, better wear, more comfortable to wear, better shrinkage level, better temperature resistant. Polyamide is on the same level as polypropylene in terms of sustainability and wear. Polyester is less workable/flexible, it is cheaper and dries quicker. Polyester gets rough and stiff after handling. Polyamide lies between Polyester and Polypropylene in terms of stiffness and roughness, as Polypropylene is the softest yarn, even after handling. Polyester and polyamide tend to sweat more as these are synthetic fibers. Polypropylene pushes the moist outside the sock so the feet keep dry.

Comfort

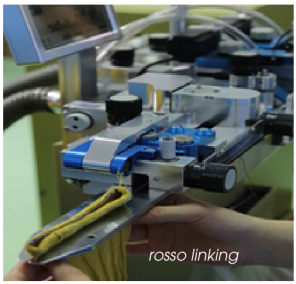
- Elasticity: how much elastane is there in the sock and how does this foster the length and width of the cleanroom sock.
- Shrinkage level: in case of reusable socks, after the socks being produced, they will be put onto a mold and steam ironing takes place (see picture). This will create the first level of shrinkage after sock production. Most of the shrinkage will take place in the first two to three cycles and then it stabilizes. This is been taken into account when producing the sock for the optimal length and width during its lifetime.

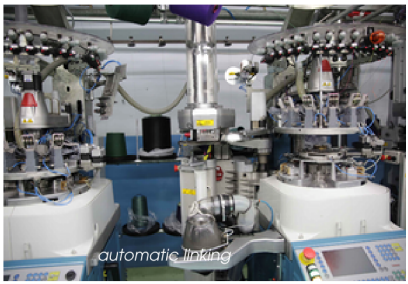
- Denier, filament, yarn thickness (see page 4)
  - > The higher denier, how thicker the sock and gives more comfort.
  - > The lower denier, the more transparent the sock and thus would not give any comfort nor protecting the environment from particles. Also the sock would more easily break or pill.
  - > Usually a single-use sock is around 40 denier and a good reusable sock around 150 denier.

steam ironing

Knitting

- There are many ways to finish the sock in a factory. You can recognize them at the very end (at the toes) how the stitching has happened. Is there a thin line over your toes, or in front of your toes (rosso linking), or is this fully prevented by weaving the sock in a flat manner (automatic linking technique). The last technique gives much comfort, whereas the other two would give an unpleasant feeling.





Costs, end-of-life and storage

- These aspects are in any case coming back to see what the impact is on pricing and if your facility is able to store socks properly and how many. E.g. order quantity determines the pricing for single-use massively, but you need to have space to store such bulk. Next to this, this will be a one-off in your CAPEX expenses.

Logistics/distribution

- How to cope with the waste? What are the costs to it?
- How to have enough in circulation, but not too much (optimum level)?
- Do you have enough storage space for all socks in the facility?
- Do you have enough space in the changing rooms?
- Do you have dispenser(s) in the changing rooms?
- How do you keep track on the consumption?
- Do you know the impact of choosing a regular sized socks over tube socks?
  - > E.g regular sized socks come in three to four sizes, meaning that you should consider at least three or four different dispensing units.

CLEANROOM SOCKS

Tests

The test is to define the differences between ‘’street socks’’ and special cleanroom socks made of different materials. Due to confidentiality the socks which have been tested are not exposed by name, but these are known at the internal test file at Elis Cleanroom under report number 1500-06.

There were three different aspects to be measured which are particle testing using a modified Helmke drum (remote nozzle of particle counter in opening Drum). Secondly, CFU tests have been taken place by placing a Rodac sample at the front and back of the sock after a day of wearing (before and after). Lastly, comfort has also been asked on the following parameters:

- No pinching by sock
- Sock stay in place
- Easy to put on
- Sweeting factor
- Warm/hot or cool effect of sock
- Common remarks

Results

Socks test												
			CFU before		CFU after		Comfort					
#	Socks type	Particle count	toe (front)	heel (back)	toe (front)	heel (back)	pinching	Stay in place	Easy put on	sweat fact.	warm/cool eff.	Remarks
1	Woolen socks (street)	1130	3	1	41	29	yes	sloppy	yes	9	warm	non-cleanroom
2	Cotton socks (street)	614	0	2	20	17	no	yes	yes	3	normal	non-cleanroom
3	Reusable Elis Cleanroom tube socks (prolen siltex 75%, 22% polyester, 3% elasthan	125	0	0	18	9	no	yes, tight	yes	3	normal	nice long
4	Reusable Tube socks (97% Polyamide, 3% Elasthan)	136	1	0	24	17	no	yes, no pinches	yes	3	normal	nice long
5	Reusable sized socks 1 (100% Polyamide)	221	2	1	19	6	no	yes	yes	3	normal	normal
6	Reusable sized socks 2 (97% Polyamide, 3% Elasthan)	275	1	3	25	10	no	yes	yes	3	normal	normal
7	Single use socks 1 (100% Polyester)	268	3	2	17	15	no	yes	yes	3	normal	normal
8	Single use socks 2 (85% Polyester, 15% Spandex)	165	0	1	21	18	no	yes	yes	5	normal	too short
9	Single use socks 3 (100% Polyester)	112	2	0	25	21	no	yes	yes	3	normal	too short
10	Reusable sized socks 3 (Unknown)	134	0	1	15	9	no	yes	yes	3	normal	short

Pricing and service

Let's assume that a reusable sock would cost you 3,00 euro per pair and washing the socks would be 30 cents per pair. A reusable sock can be washed easily 50 cycles. If we assume that washing takes place once a week, then the socks will last for one year. In this case, a reusable sock would cost you 18 euro.

On average a disposable sock costs 0,40 euro per pair. This means that you spend 20 euro on disposables when using 50 times a disposable pair.
This is now excluding the transportation costs and logistics, where you also would encounter costs for.

Apart from the extra single-use costs, this would give you a saving of eleven percent when choosing reusable socks. Next to this, the CSR aspect of throwing all these socks away is massive. To put it very straight forward, 49 times more landfill than choosing reusable.
Also here one could dwell on transportation costs from the laundry to the end-user premises, using chemicals, wash water, etc. or on the other hand the big bulk containers from China which is quite a distance.
Yes, but it needs to be placed into perspective as every situation is different and therefore, also exact CSR outcome differs. Thus, looking closely to the product only, 49 times more landfill.

But again, decisions are not only to be made based on CSR or pricing. The end-users need to wear it and need to be comfortable, and decisions are to be made as been described on page 7.

Conclusion

Now that the Annex 1 is stating clearly cleanroom socks should be worn in grade B and C areas, this is mainly to force companies to replace regular ''street'' socks to actual cleanroom dedicated socks. Nevertheless the socks are worn over the bare skin of the operator, but partially covered by the cleanroom shoe (75%) and in a A/B classified cleanroom also covered by a cleanroom boot as part of the full cleanroom garment (overall, hood).

Based on all the info given on how to choose a cleanroom sock, considering material, comfort, knitting opportunities, pricing, logistics and so on, the difference between the cleanroom socks and the non-cleanroom socks (woolen and cotton socks) is clear as can be seen in the test execution (page 9). Non-cleanroom socks are spreading much more particles than all the cleanroom socks which have been tested. Also the amount of CFU present on the ''street socks'' is significantly higher than with cleanroom socks. The cause of this effect is possibly the warm effect and therefore sweating while wearing. Then there is still a distinction between single-use and reusable cleanroom socks in which the single use socks are all too short and some did not even cover the ankle. Next to this, the fabric is also very open which could give particles.

The reusable socks are all good for cleanroom environments and the total difference between them is not that big in relation to particles, but here the design and therefore the operational challenges and comfort could give guidance on what to choose.
If one knows that all the chosen material is good enough for the cleanroom, then the best way to move forward is to make a short list based on the key-parameters (design, logistics, costs etc.) and test it inside the cleanroom for multiple days with your operators.

This makes the operators involved, committed and creates buy-in in the whole journey of picking the right cleanroom sock.

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