Impact of processes certification on the liability of anti-dust mites bed covers

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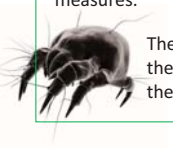
In relation to this presentation, I declare that there are no conflicts of interest.

Anti-dust mites covers

Simply killing dust mites does not remove allergens, several measures are essential to lower allergens and improve symptoms of allergic patients. Anti-mites covers are the most relevant device for allergen eviction[1].

Anti-mite barrier covers are manufactured from textiles with filtration properties usually validated by different certification labels. Although only textile certifications are mandatory, some covers are manufactured using processes ISO 13485[2] certified, subjecting covers to more stringent quality control measures.



The objective of the study was to evaluate the benefit of ISO 13485 certification on the liability of the final product.

Medical devices

In Europe, medical devices are designed and manufactured in compliance with directives 93/42/CEE[3]. Devices complying with those directives are entitled to display CE marking.

There are four classes of medical devices, ranging from low risk to high risk (Figure 1). Anti-dust mites covers are class one medical devices.

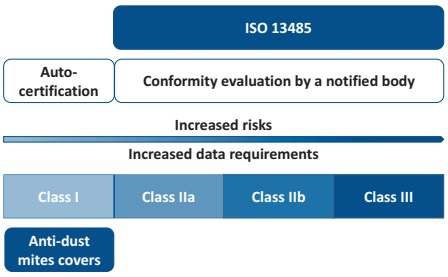


Figure 1 : European classification and regulatory requirements for medical devices.

ISO 13485 certification

International Organization for Standardization (ISO) standard 13485 presents the requirements for a quality management system for the design and manufacture of medical devices.

The norm ISO 13485 guarantees, with regular audit :

- The mandatory justification of the medical benefit.
- Product conformity to quality standard.
- Risk analysis throughout products development.
- Strict controls on all processes, from design to manufacturing.
- The control of the communication by a certification approved by European health authorities.

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Conformity assessment procedures

Manufacturers of class 1 medical devices are only required to provide a self-declaration of safety and performances, while ISO 13485 certification requires well-defined processes and strict recording (Figure 2).

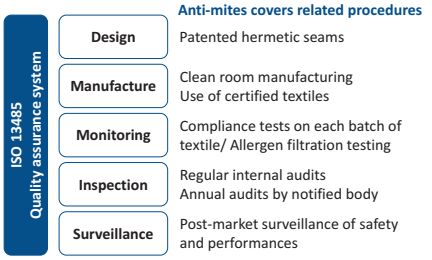

Figure 2 : ISO 13485 full Quality assurance system

Methods

In this study, three different batches of micro-woven (MWC) and non-woven polyester polyamide (NWP) textiles went through the quality control processes required by the norm ISO 13485.

Textiles pore sizes were measured using an optical microscope (Bresser, USA).

Textile permeability was tested using a Rotomitest, apparatus composed of two compartments separated by the sample. Der p1 allergens were placed in compartment 1 and the apparatus was set to rotate for 18 hours (Figure 3).

Der p1 allergens that passed through the sample to compartment 2 were then measured with a Der p1 ELISA kit (Citeq Biologics, Netherlands).

Results

Microphotographs of textiles (Figure 4 A,B and C) clearly show that anti-dust mites certified textiles (micro-woven/Texaal® Cotton and non-woven polyester polyamide/Noxaalon®) have a higher density of fiber when compared to cotton used to make common bed covers. Permeability testing of those fabrics (Figure 4 D) shows that both anti-dust mites certified textiles possess the required filtration properties.

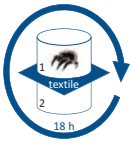

Figure 3 : Rotomitest principle. Allergens are placed in compartment 1 and collected in compartment 2 after 18h.

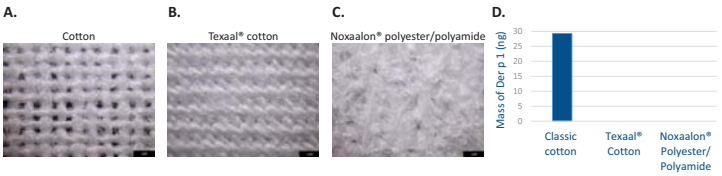

Figure 4 : Representative microphotographs and filtration properties of tissues used. A. common cotton, **B.** Micro-woven cotton (MWC), **C.** non-woven polyester polyamide (NWP) and **D.** Permeability results of common cotton, MWC and NWP obtained using the rotomitest apparatus, showing the amount of allergen that passed through the fabrics, from compartment 1 to compartment 2.

Three batches of both anti-dust mites certified textiles were tested according to ISO 13485 monitoring processes. NWP fabrics showed irregular pore sizes, with 2 batches having pore size greater than 5 µm (Figure 5) while MWC showed similar pore sizes for all 3 batches. Permeability results (Figure 6) show that 2 batches of NWP fabrics are significantly more permeable to Der p1 allergen compared to MWC tissue (23,6ng +/- 0.7 vs 3,4ng +/- 0.02).

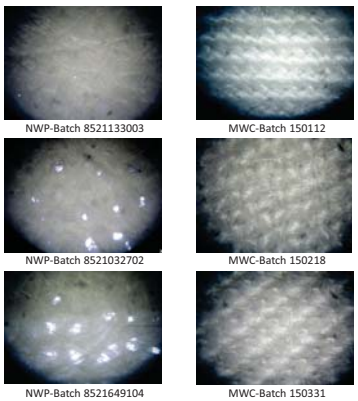

Figure 5 : Microphotographs of 3 batches of NWP fabrics and 3 batches of MWC fabrics, showing 2 batches of NWP with irregular pore sizes (> 5 µm).

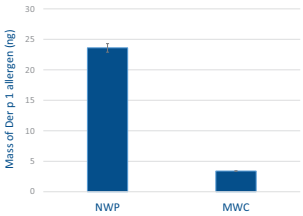

Figure 6 : Permeability results showed that NWP fabrics are significantly more permeable to Der p1 allergen compared to MWC tissue (23,6ng +/- 0.7 vs 3,4ng +/- 0.02).

Thus, ISO 13485 quality controls allowed for dismissal of 2 out of 6 batches of unsatisfactory NWP textiles.

References

[1]Lau S. Allergen Avoidance as Primary Prevention: Con." Clin Rev Allergy Immunol 2005 ; 28: 17–23.

[2]ISO 13485:2012 : Medical devices – Quality management systems..

[3]Council directive 93/42/EEC from the council of the European Communities of 14 June 1993 relating to the placing on the market of medical devices.

Conclusion

In addition to the initial test on textiles, as for medical devices of higher class, monitoring manufacturing processes certification is necessary to ensure the quality of the finished product, especially when using non-woven fabric. Therefore, ISO 13485 certification is a relevant criteria for anti-mite covers quality and thus effectiveness.

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ISO 13485 certification is not required for anti-mite covers, but it is a pledge of quality