

EVIDENCE BASED STATEMENT

DOMAIN **09**, Statement **01**

TOPIC: “Compression stockings certification requirements”

SEARCH TERMS & SOURCES

(compression stockings) AND (classification)

INCLUSION CRITERIA

- Lower limb only
- Systematic Reviews, Meta-Analysis, Reviews, RCT
- Publication < 10 years, only ENG

SEARCH RESULT BEFORE - AFTER SELECTION

11/4

PERTINENT LITERATURE NOT IDENTIFIED BY THE LITERATURE SEARCH

1. Office of the Surgeon General (OSG). Confronting Health Misinformation: The U.S. Surgeon General’s Advisory on Building a Healthy Information Environment [Internet]. Washington (DC): US Department of Health and Human Services; 2021. References. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK572167/>
2. Berszakiewicz A, Sieroń A, Kasiński Z, et al. Compression therapy in venous diseases: current forms of compression materials and techniques. *Postepy Dermatol Alergol.* 2020;37(6):836-841.
3. Anderson I. Optimising concordance with compression hosiery in the community setting. *Br J Community Nurs.* 2015 Feb;20(2):67-8, 70, 72.
4. Bovenschen HJ, Booij MT, van der Vleuten CJ. Graduated compression stockings for runners: friend, foe, or fake? *J Athl Train.* 2013 Mar-Apr;48(2):226-32.
5. FDA product classification: <https://www.accessdata.fda.gov/>

EVIDENCE BASED STATEMENT

Domain 9; Statement 1

IDENTIFIED REFERENCES

1. Knight Nee Shingler SL, Robertson L, Stewart M. Graduated compression stockings for the initial treatment of varicose veins in people without venous ulceration. *Cochrane Database Syst Rev.* 2021 Jul 16;7(7):CD008819.
2. Dissemond J, Assenheimer B, Bültemann A, et al. Compression therapy in patients with venous leg ulcers. *J Dtsch Dermatol Ges.* 2016 Nov;14(11):1072-1087.
3. Neumann HA, Partsch H, Mosti G, Flour M. Classification of compression stockings: report of the meeting of the International Compression Club, Copenhagen. *Int Angiol.* 2016 Apr;35(2):122-8.
4. Shingler S, Robertson L, Boghossian S, Stewart M. Compression stockings for the initial treatment of varicose veins in patients without venous ulceration. *Cochrane Database Syst Rev.* 2013 Dec 9;(12):CD008819.

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TEXT FOR INCLUSION IN THE DOCUMENT

DOMAIN 01, Statement 01, TOPIC: “Compression stockings certification requirements”

Graduated compression stockings represent a pivotal tool for venous-lymphatic disease management.

Their prescription requires appropriate knowledge by the health professional indicating them, as well as by the patient who must understand why proper use and compliance is crucial. The prescribers and users must also be extremely careful in not being victims of the many not certified products claiming effects that have actually not been demonstrated.

[Bovenschen HJ, Booij MT, van der Vleuten CJ. Graduated compression stockings for runners: friend, foe, or fake? J Athl Train. 2013 Mar-Apr;48(2):226-32].

Currently, there are several compression hosiery classification systems. The most common one is the RAL-GZG (the German Institute for Quality Assurance and Certification) which is used for certification. The two remaining ones include the CEN (The European Committee for Standardisation) classification and the simplified ICC (International Compression Club) classification. In all classifications a pressure range (in mmHg) exerted by the product at the ankle level assessed has been proposed as a more uniform criterion.

[Neumann HA, Partsch H, Mosti G, Flour M. Classification of compression stockings: report of the meeting of the International Compression Club, Copenhagen. Int Angiol. 2016 Apr;35(2):122-8]

***[Berszakiewicz A, Sieroń A, Krasinski Z, Cholewka A, Stanek A. Compression therapy in venous diseases: current forms of compression materials and techniques. Postepy Dermatol Alergol. 2020;37(6):836-841]**

The medical compression stocking is considered as a medical device, therefore it must demonstrate specific characteristics, including CE mark or FDA approval in the related countries. The FDA considers compression stockings as a class I device exempt from FDA 510k pre-market notification requirements. An official independent certification institute for graduated compression stockings is missing in USA up to our knowledge.

[FDA product classification <https://www.accessdata.fda.gov>]

Wherever present, the certification test includes the safety of the used material and the pressure course. Other supplementary tests investigate possible changes in compression behavior during rest phases as well as the wear-out of the product. The certification must assess also the microclimate between the skin and the stocking, as well as the presence of eventual harmful substances and the odor management. The fit of the product is measured to verify the adaptation to the different leg sizes. In case nanomaterials, silver additives, pharmaceutical are used, a higher classification and testing is needed and the product can become class Iia, I Ib, III according to the Medical Device Regulation, based also on the associated risk. Increasing awareness on the certification and regulatory aspects is of paramount importance for avoiding ineffective inappropriate products use and to maximize the benefits an appropriate compression demonstrated to bring.

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STATEMENT FOR PUBLIC EVIDENCE-BASED AWARENESS

DOMAIN 09, Statement 01

“Compression graduated stocking must be certified, report the exerted pressure in millimeters of mercury and be indicated by an expert health-professional”

SELECTED REFERENCES

1. Bovenschen HJ, Booij MT, van der Vleuten CJ. Graduated compression stockings for runners: friend, foe, or fake? *J Athl Train.* 2013 Mar-Apr;48(2):226-32
2. Neumann HA, Partsch H, Mosti G, Flour M. Classification of compression stockings: report of the meeting of the International Compression Club, Copenhagen. *Int Angiol.* 2016 Apr;35(2):122-8
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4. FDA product classification <https://www.accessdata.fda.gov>

identified LITERATURE BIAS

Paucity of performance comparisons among the different certification systems

SUGGESTED NEXT LINES OF RESEARCH

1. Registry on certified vs not certified products use