



ISO 13404-1

**Prosthetics and orthotics —
External orthoses and orthotic
components —**

**Part 1:
Uses, functions, classification and
description of lower limb orthoses**

*Prothèses et orthèses — Orthèses externes et composants
d'orthèses —*

*Partie 1: Utilisations, fonctions, classification et description des
orthèses pour les membres inférieurs*

**First edition
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This document was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

This first edition of ISO 13404-1 cancels and replaces ISO 13404:2007, which has been technically revised.

The main changes are as follows:

- introduction of a new [Clause 4](#) on uses;
- update of [Clause 5](#);
- [8.4.5](#) has been renamed “Control and activation” and its content has been updated to reflect the development of modern orthotic components;
- addition of functional electrical stimulators to [Clause 8](#).
- a focus on lower limb orthoses.

A list of all parts in the ISO 13404 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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This document is intended for practitioners prescribing and/or providing external lower limb orthoses, for manufacturers describing their products, and for those researching and reporting on orthotic use.

External lower limb orthoses are used to treat a wide range of impairments of body functions and structures that impact the lower limb and to assist in overcoming limitations during everyday activities.

Definitions of prefabricated, adaptable, user-matched and custom-made orthoses were changed due to international regulations. Users can refer to the applicable national regulatory documents for details in definitions and local differences in terminology and responsibilities.

Uses, functions, classification, method of fabrication, types, and components of the orthotic device should be described within general healthcare procedures.

For further specifics on foot orthoses, refer to ISO 21064 and for further specifics on soft orthoses for the lower limb, refer to ISO 21063.