Custom Made Shoes high-quality and modern service made to measure = custom-made products

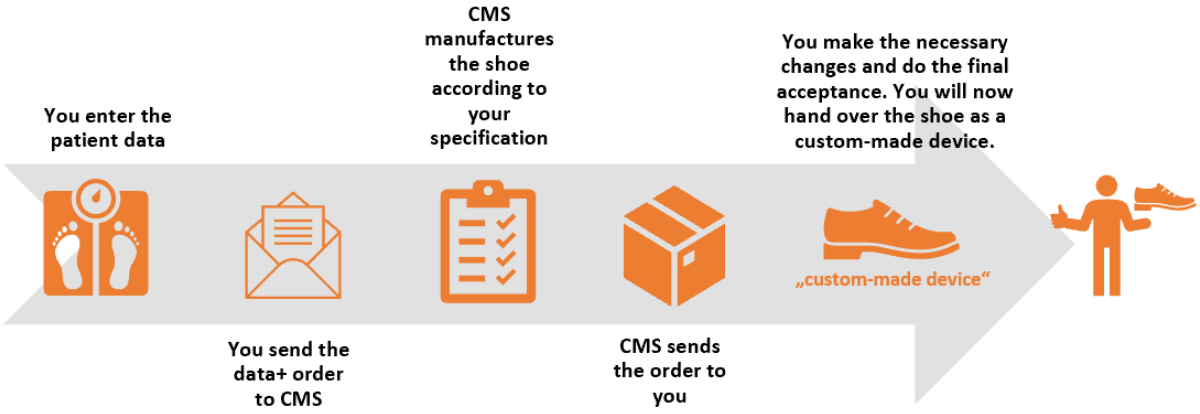
- Information about CMS and MDR – Medical Device Regulation (2017/745/EG)

All medical devices that are individually manufactured for a customer, must be evaluated and documented by the manufacturer of the custom-made device (e.g., health workers) in accordance with Annex XIII and MPDG (formerly MPG).

Custom-made shoes and made-to-measure uppers that are individually manufactured by you for a patient are custom-made according to the MDR. Finally, the finished shoes are adapted to the needs of your patient according to your specifications and are only to be used by this patient.

CMS -Custom Made Shoes – can support you in this process as an „extended workbench".

CMS as an extended workbench – how does it work?



Insofar as direct skin contact with the shoe lining is intended, the CMS shoes are subjected to a pollutant assessment.

What do you have to consider as a manufacturer of such a custom-made product?

The procedure for custom-made products is described in Annex XIII of the MDR:

- Prepare a statement
  - Name & address of the service provider, as well as of all production facilities
  - Necessary Data to identify the device
  - Declaration that the device was made for a specific patient (name, acronym, or patient number for identification)
  - Name of the person who prescribed the device in question and who is authorized to do so, based on professional qualifications under national legal provisions
  - Specific features of the device as stated in the regulation
  - Declaration of compliance with the essential requirements according to Annex I
- Keeping the documentation available for national authorities, which includes the design, production, and performance of the product to assess the fulfillment of the requirements of the regulation
- Measures for manufacturing processes to match the documentation of the manufactured device
- Retention of the declaration for at least 10 years
- The service provider checks and documents the subsequent phases after production in accordance with Annex XIV Part B and makes any necessary corrections
- Reporting serious incidents in accordance with Article 87, Paragraph 1

Have we piqued your interest? We would be happy to advise you on all aspects of CMS.

Phone.: +49(0)2191910-206 Mail: cms@schein.de Fax: +49(0)219191028-206