

## Safety statement for Materials and Substances

Dear customer,

Ottobock SE & Co. KGaA, Max-Näder-Strasse 15, D-37115 Duderstadt declares herewith that all materials, substances and components supplied are, within their intended use and under consideration of the processing guidelines as specified in the instructions for use, suitable for the fabrication prostheses and orthoses.

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According to Article 2, section 3 of the Regulation (EU) 2017/745 on medical devices (MDR), manufacturers have the responsibility to select all materials, substances or components which they intended to use to fabricate custom-made devices, in a way that the individual patient solution (custom-made medical device) fulfils the general safety and performance requirements pursuant to the defined intended use.

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We would like to support you in the best possible way in fulfilling your obligation of proof for each custom-made device you manufacture. After long-standing and permanent usage of our materials we are not aware of any events which point out an unacceptable risk in using these materials and products for the fabrication of prostheses and orthoses.

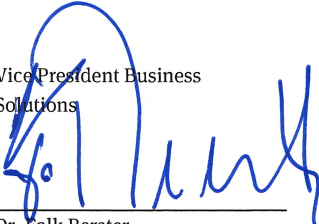
Our service for you:

We create and manage all required evidence and make sure that it is at your disposal in case of need.

**Duderstadt 2021-10-14**

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Vice President Business  
Solutions




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Dr. Falk Berster

Ottobock SE & Co. KGaA

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