

Otto Bock Mobility Solutions GmbH | Lindenstraße 13 | 07426 Königsee

To whom it may concern

25. May 2021

**Obligation to communicate information according to article 33
REACH-Regulation (EC No 1907/2006)**

By the CE-Marking and the Declaration of Conformity of our medical devices we confirm that our products fulfil the "General Safety and Performance Requirement" of the Medical Device Regulation 2017/745/EC of 5 April 2017.

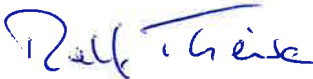
This confirmation includes, that our medical devices are designed and manufactured in such a way as to ensure that, if used under intended conditions and for intended purposes, they neither put a risk at the patients' safety nor present a possible hazard to users or other persons. Corresponding investigations are carried out, amongst others, as part of our risk management system according to ISO 14971.

According to the European Regulation for Chemicals REACH (Registration, Evaluation and Authorization of Chemicals), we are obligated to disclose information about products that contain substances stated on the "candidate list", if the substance is present at more than 0.1 % of the mass of the object. Within the scope of our supplier's management, we have obliged our suppliers to inform us immediately, if the allowed concentration of such a substance in a product/component is exceeded.

Otto Bock will inform its customers unsolicited once information is given that listed substances are contained in supplied products above the concentration of 0.1% specified per REACH.

Otto Bock Mobility Solutions GmbH wants to point out that there is no legal obligation for providing confirmations as far as no listed substances above the specified concentration in the products supplied.

Yours sincerely



Ralf Theisen
Managing Director



Björn Kölle
Person Responsible
Regulatory Compliance

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