

REACH Statement of Conformance

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

With the CE marking and the EU Declaration of Conformity for our medical devices we confirm that Össur products comply to requirements of regulation (EU) 2017/745 of the European parliament and the council (MDR). This confirms that the products are designed and manufactured in such a way, that if used according to intended purpose and conditions, they will not pose a risk to the user.

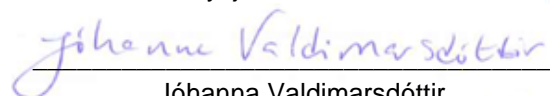
Össur hf. acts as a producer, importer, and supplier of articles according to article 3 of the European regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Össur evaluates products with regard to substances of very high concern (SVHC) and according to change notification agreements suppliers must notify Össur of any changes to raw materials. Össur also monitors regular updates of the Candidates list of SVHC.

Based on this Össur declares that to the best of our knowledge our products do not contain any substances listed on the SVHC above the 0.1% weight by weight.

Authorized signatory:

Reykjavík, 2023-06-01



Jóhanna Valdimarsdóttir
VP of Quality & Regulatory