

## Environmental and Social Data Sheet

### Overview

Project Name:	Oessur Medical Technology RDI
Project Number:	2019-0524
Country:	Iceland
Project Description:	The project concerns the promoter's R&D investments for innovative prosthetics and bracing solutions.
EIA required:	no
Project included in Carbon Footprint Exercise:	no

### Environmental and Social Assessment

#### Environmental Assessment

The project concerns investments in R&D activities (laboratory research, software design, mechanical engineering, process development, clinical studies, etc.), which are a central part of the promoter's operations and will be embedded in the existing organisational and management structure. The project will not result in any residual environmental impact, as it will be carried out in existing and authorised research facilities. Such R&D activities do not fall under the EU's Environmental Impact Assessment (EIA) Directive 2014/52/EU amending Directive 2011/92/EU, as a result an EIA is therefore not required. The operating procedures in place are in line with best industry standards and are regularly audited externally.

#### Other Environmental and Social Aspects

The promoter utilises environmental management systems and safety programmes and is conducting its business in compliance with all applicable environmental laws and regulations. Össur's biggest manufacturing and distribution sites have an environmental management system certified according to ISO 14001:2015. Employee safety is Össur's first priority. Fifteen Össur locations around the world take part in the Safety Program, the key focus areas of which are Employee Safety, Operational Safety and Employee Participation. The program's goal is to continually improve the safety management system to ensure a safe work place.

According to its environmental policy, Össur aims to minimise its environmental impact by:

- Preventing, reducing, or controlling waste and pollution from operations;
- Meeting all applicable environmental compliance obligations and commitments;
- Focusing on continual improvement of the environmental management system by meeting its objectives;
- Encouraging employee participation;

Össur continually improves its environmental performance in a sustainable and effective manner by working on improvements within the following environmental focus areas:

- Emission to air and water;
- Waste management;
- Chemical Product Management;
- Sustainable Product Design;
- Employee empowerment.



In 2018, 57% of energy consumed by Össur was from renewable energy sources, resulting in a Renewable Energy Intensity factor of 1.3. The promoter has achieved a 33% reduction in hazardous waste since 2016.

Chemical Product Management is an important part of Össur's operations as various chemical products classified as hazardous are used in the manufacturing of medical devices. One of Össur's legal obligations is to ensure employee access to Safety Data Sheet (SDS) for chemical products they use or may be exposed to during their work. In 2018, a global solution for SDS management was implemented at Össur providing an improved global overview of chemical products used. This improved overview will aid Össur's efforts to substitute hazardous chemical products with less hazardous ones, to improve employee safety and reduce pollution from hazardous waste.

Sustainable Product Design is now part of Össur's R&D Strategy where development teams will receive continuous education and tools to further advance in this area and facilitate sustainable decision making throughout the development phase of products, services and packaging.

Össur has had a certified quality management system in place since 1993, based upon ISO 13485 management standards for medical devices. The quality management system also complies with the applicable medical device regulations in the countries that Össur sells to, including but not limited to the requirements of the FDA Quality System 21CFR820, the European Medical Device Directive EU 93/42/ECC and the Canadian Medical Device regulation SOR/98-282.

Össur has been committed to the UN Global Compact principles since 2011.

The project's research activities aim to provide new and improved medical devices that are more effective and better tolerated, resulting in a positive impact on patients' quality of life through helping them regain their mobility and reducing the need for surgery. By providing people with more functional products, it will allow them to be more active and able to lead a healthier life, which will result in decreased cost for the healthcare systems. Therefore, the project is expected to bring significant positive social impacts.

## **Conclusions and Recommendations**

The project concerns investments in research and development that will be carried out in existing facilities without changing their already authorised scope. Such R&D activities do not fall under the EU's Environmental Impact Assessment (EIA) Directive 2014/52/EU amending Directive 2011/92/EU, as a result an EIA is therefore not required. The promoter has an integrated environmental management policy and effective operating procedures in place which are in line with best industry standards.

Considering the above, the project is acceptable for Bank financing in environmental and social terms.