

Luxembourg, 17 October 2018

**Public**

## Environmental and Social Data Sheet

### Overview

Project Name: CARMAT – ARTIFICIAL HEART (EGFF)  
Project Number: 2018-0345  
Country: France, Czech Republic, Denmark  
Project Description: Founded in 2008, Carmat is a French medtech company that is developing an artificial heart.

EIA required: no  
Project included in Carbon Footprint Exercise<sup>1</sup>: no

### Environmental and Social Assessment

#### Environmental Assessment

Carmat is responsible for the design and development of the world's most advanced total human, bio-compatible and self-regulating, artificial heart (TAH). The TAH has the potential of offering a long-term therapeutic solution to patients with advanced biventricular heart failure who are waitlisted for a suitable donor, or not eligible for transplantation having exhausted all treatment options. Carmat's product must satisfy the Key Requirements of the Directives 90/385/EEC (concerning active implantable medical devices) and 93/42/EEC (concerning medical devices) to obtain the CE marking.

The investments to be financed concern research, development and innovation activities that will be in the medical devices sector, enabling the company to advance to the market approval process (CE labelling) of the lead product, while working on second generation artificial hearts with improved features.

The project's activities are not listed in any of the annexes of the EU Directive 2011/92/EU as amended by 2014/52/EU. Furthermore, the project will be carried out in existing facilities already authorised for similar activities and volumes. Therefore, an Environmental Impact Assessment (EIA) is not required. In addition, the Company's quality control system has been certified by a third-party organisation in accordance with the regulatory requirements of the applicable European Directive 93/42/EEC and the reference standards on quality management (ISO 9001 and ISO 13485). CE marking via the declaration of CE compliance is based on a complete audit of the quality assurance system with an assessment of all the Company's processes and focusing on activities linked to the product.

The use of animal testing is minimised and in line with the EU Directive 2010/63/EU.

#### Other Environmental and Social Aspects

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<sup>1</sup> Only projects that meet the scope of the Pilot Exercise, as defined in the EIB draft Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: above 100,000 tons CO<sub>2</sub>e/year absolute (gross) or 20,000 tons CO<sub>2</sub>e/year relative (net) – both increases and savings.

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Carmat has a sound Safety Health and Environment (SHE) policy, including a commitment to comply with legal requirements, pollution prevention and continual improvements and undertakes regular audits. The project, if successful, is expected to lead to significant social benefits. Evidence based treatment of chronic heart failure is demonstrated to be effective in lowering morbidity and mortality as well as cost-effective from an economic point of view.

## Conclusions and Recommendations

Overall, the project can be classified as acceptable with positive or no residual impact. If successful, the project presents high potential health and social benefits for society. The project is therefore considered acceptable for EIB financing in environmental and social terms.