



Luxembourg, 13 December 2023

Environmental and Social Completion Sheet (ESCS)¹

Overview

Project Name:	CARMAT – Artificial Heart (EGFF)
Project Number:	20180345
Country:	France, Czech Republic, Denmark
Project Description:	Founded in 2008, Carmat is a French medtech company that is developing an artificial heart.

Summary of Environmental and Social Assessment at Completion

EIB notes the following Environmental and Social performance and key outcomes at Project Completion.

Carmat, a French commercial stage Medtech company, is the designer and developer of the world's most advanced total artificial heart.

To obtain market access and the CE mark (obtained in 2020), Carmat's product satisfied the Key Requirements of the Directives 90/385/EEC (concerning active implantable medical devices) and 93/42/EEC (concerning medical devices).

The project concerned the Promoter's R&D investments across several EU countries to design and develop an advanced cardiovascular prosthetic device and as well as gain market access and strengthen the company's manufacturing processes and capabilities. Such R&D activities do not fall under the EU's Environmental Impact Assessment (EIA) Directive 2014/52/EU amending Directive 2011/92/EU. Furthermore, the project was carried out in existing facilities already authorized for similar activities and volumes that conforms to European quality control standards (European Directive 93/42/EEC and the reference standards on quality management ISO 9001 and ISO 13485).

Other Environmental and Social Aspects

Carmat's product is the most advanced total artificial heart and provides an important option for patients with heart failure in the context of limited availability of donor hearts. Carmat's IP and know-how (technological, clinical and regulatory development, assembly and supply chain etc.) will contribute to the competitive search for, and generation of, new European knowledge in areas that are vital to the improvement of the health of its citizens, along with a better understanding and treatment of cardiac diseases.

Summary opinion of Environmental and Social aspects at completion:

EIB is of the opinion based on reports from the promoter that the Project has been implemented in line with EIB Environmental and Social Standards, applicable at the time of appraisal.

¹ The template is for ILs and FLs