European Investment Bank

Luxembourg, 19th December 2024

Public

Environmental and Social Data Sheet[1]

Overview

Project Name:	GVM ADVANCED MEDICAL DEVICES RDI
Project Number:	2024-0118
Country:	Italy
Project Description:	The Project supports the Promoter's investments in (i) research, development and manufacturing capabilities for medical devices in the cardiovascular and respiratory therapeutic areas, (ii) clinical and translational research for cardiovascular and metabolic diseases and (iii) digitalisation of its healthcare infrastructures across Europe over the period 2024-2027.
EIA required:	no
Invest EU sustainability proofing required	yes
Project included in Carbon Footprint Exercise[2]:	no

(details for projects included are provided in section: “EIB Carbon Footprint Exercise”)

Environmental and Social Assessment

Environmental Assessment

The Project consists of a four-year investment plan (2024-2027) to be implemented by healthcare group GVM (*Gruppo Villa Maria*) and its subsidiaries, focused on the development and manufacturing of medical devices, research and digitalisation activities. More specifically, the Project covers three areas, namely:

i. Research and development activities on medical devices for cardio-pulmonary conditions. This will also include the construction of new infrastructure to accommodate the expansion of the company’s existing manufacturing facility in Medolla (Modena), Italy, including new cleanroom, laboratory, production, and training areas.

ii. Clinical and translational research on cardio-vascular and metabolic diseases, to be performed at GVM’s hospital in Cotignola (Ravenna), Italy, as well as in other clinics of the group in Italy and abroad.

iii. Digitalisation investments at GVM’s group level, including both hardware (data centres, data lakes, network upgrades, etc.) and software (clinical decision support systems,

[1] The information contained in the document reflects the requirement related to the environmental, social and climate information to be provided to Investment Committee as required by the Invest EU Regulation and it represents the equivalent of the information required in the template of the InvestEU sustainability proofing summary

[2] Only projects that meet the scope of the Carbon Footprint Exercise, as defined in the EIB Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: 20,000 tonnes CO2e/year absolute (gross) or 20,000 tonnes CO2e/year relative (net) – both increases and savings.

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enterprise imaging solutions, Hospital Management System, eHealth solutions, etc.), aligned with the shift towards a more digitalised healthcare environment.

The manufacturing activities to be carried out at point i) above are regarded equivalent to projects listed under Point 10.b Urban Development Projects within Annex II of the EIA Directive 2014/52/EU, amending Directive 2011/92/EU. However, according to Annex 3 of Italian law No. 152/2006 (and its subsequent amendments) transposing the EIA Directive in Italy, said activities are not subject to an Environmental Impact Assessment procedure.

The Company's intended expansion plan at point i) above (construction of production building and R&D offices adjacent to the existing site) is part of an Urbanistic Implementation Plan (PUA in Italian language), which allows construction through Direct Intervention (meaning by providing a building permit only). Nevertheless, the plan required an A.U.A. (*Autorizzazione Unica Ambientale* = Single Environmental Permit) to be issued by the competent authority, covering water, air quality, and noise - received by the Promoter on 13th December 2023, under Ref. n. DET-AMB-2023-6557.

The building permit for the expansion of GVM's subsidiary existing facility in Medolla (Modena) has already been issued by the local authority.

Regarding the other components of the Project, points ii) and iii) involve research, development and digitalisation activities to be carried out by the Promoter in existing facilities which do not need changing their already authorised scope. The research and development activities of the Project, as well as the digitalisation components, are not subject to an EIA procedure according to Directive 2014/52/EU amending Directive 2011/92/EU.

Climate Assessment

According to the project design, the construction of the new infrastructure is expected to contribute to Climate Action, in relation to the Climate Mitigation pillar covering Energy Efficiency and Renewable Energy. This is achieved through the implementation of technical solutions for heating and heat exchangers allowing energy savings in the order of approx. 600 MWh/y. In addition, approx. 400 MWh are expected to be generated from renewable sources to be installed in the new construction (i.e., rooftop photovoltaic panels). The total energy saving has been estimated at approx. 1,000 MWh/y, equivalent to saving approx. 530 tCO_2e/y.

The Promoter carried out a Climate Risk Vulnerability Assessment, the residual Climate Risk profile of the investment has been assessed as Low.

EIB Paris Alignment for Counterparties (PATH) Framework *If the counterparty is <u>not</u> in scope of the PATH framework, delete this section including this heading*

The counterpart GVM is in scope and screened out of the PATH framework, because it is not considered high-emitting and having high climate vulnerability.

The Project has been assessed for Paris alignment and is considered to be aligned against low-carbon and resilience goals against the policies set out in the Climate Bank Roadmap, in particular the compliance with the EU Energy Performance of Buildings Directive and its transposition.

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Social Assessment

The Promoter is expected to comply with all applicable labour and social legislation. The Company's focus on labour standards and health and safety issues is regarded adequate. With the appropriate management systems in place the social risks and impacts are considered to be low. No social risks or issues are expected during the Project's implementation.

Other Environmental and Social Aspects

The Project contributes to implement UN Sustainable Development Goals (SDGs), notably SDG 3 – Ensure healthy lives and promote wellbeing for all ages, and SDG 9 – Build resilient Infrastructure, promote sustainable industrialisation and foster innovation.

Regarding the Promoter's capacity, the Promoter will leverage on its knowledge and experience in the production of medical devices and the provision of health services, as well as on the collaborations and partnerships with other players, such as consultants and customers. The Promoter has implemented a Quality Management System certified according to ISO 13485, and an Environmental Management System (EMS) according to ISO 14001.

Conclusions and Recommendations

The Project concerns investments in research, development and digitalisation for which significant environmental impacts are not expected. Moreover, the Project supports the Promoter's manufacturing capacity for medical devices, notably in relation to the expansion of the existing production facility in Italy, which did not require an Environmental Impact Assessment.

The Bank has reviewed the environmental and social capacity of the Promoter, including its organisation and processes, and deem them to be adequate and in line with industry standards.

Sustainability proofing conclusion: the Project is carried out in compliance with applicable national and EU environmental and social legislation. Under these conditions and based on the environmental, climate and social (ECS) information made available by the Promoter and the mitigation measures, the Project is deemed to be acceptable in terms of ECS risks and impacts. No further sustainability proofing is required.

Considering the above, the overall environmental and social rating of the project is considered acceptable, with only minor negative residual impacts. The project is therefore deemed acceptable for EIB financing from an environmental and social point of view.