Annex to the guarantee request from			
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Sustainability Proofing Summary <sup>1</sup>			
The summary <sup>2</sup> is in line with the sustainability proofing guidance and should be presented only for direct financing.			
Identification of the project			
Project total cost	□ below EUR 10 million		
(exclusive of VAT):	X equal to or higher than EUR 10 million		
If the project is exempted from screening/proofing based on the threshold, please mention this			
together with a short confirmation of legal compliance			
EIA Directive			
	□ Annex I projects (EIA required)		
	□ Annex II projects (screening)		
	□ EIA required (project screened in)		
	☐ EIA not required (project screened out)		
	2014 EIA Directive applicable		
	□ Yes		
	X No		
Sustainability proofing	X Climate		
process	X Environmental		
•	X Social		
Climate Dimension			
Legal framework	Applicable legislation and compliance of the operation (e.g. if part of an		
	EIA).		
	Based on the information provided by the Final Recipient and on the		
	requirements set by the Concession Agreement, the project shall comply,		
	among others, with the following legislations: SWD (2030) 55 final and		
	Directive 2010/75/EU - Directive on Industrial Emissions (IED).		
Climata dimension	Adamtatian,		
Climate dimension	Adaptation:  Describe the basis for not undertaking the climate risk assessment based		
(screening)	Describe the basis for not undertaking the climate risk assessment based		
	on the results of the climate vulnerability assessment.		
	Please refer to Section "Climate adaptation (proofing)" below.		
	Mitigation:		
	Is the project recommended to undergo Carbon footprint as per Chapter		
	2.2 of the sustainability proofing guidance?		
	□ Yes		
	X No		

<sup>&</sup>lt;sup>1</sup> In line with Article 8 (5) of the InvestEU Regulation and the sustainability proofing guidance (C(201)2632 final).

<sup>&</sup>lt;sup>2</sup> In line with section 3.2 of the Investment Guidelines, the sustainability proofing summary shall be made public after the Investment Committee has approved the use of the EU Guarantee for a specific operation (with due regard to rules and practices regarding confidential and commercially sensitive information)

If "no", justify why the Carbon footprint is not necessary. Provide any other considerations to take into account:

The climate assessment is not necessary because, according to the Sustainability Proofing Guidelines, Research and Development activities don't require a Carbon footprint assessment unless the project is expected to result in significant CO2 or other greenhouse gas emissions.

Climate adaptation (proofing), as applicable

Confirm the use of the 'Technical guidance on climate proofing of infrastructure in the period 2021-2027' for the infrastructure projects.

Describe the climate vulnerability assessment and its main conclusions.

Describe the basis for undertaking proofing.

Describe the conclusions of the climate risk assessment.

Describe the climate adaptation measures put in place.

Describe the residual climate risks and justify why they are acceptable.

## **Verification:**

Describe the independent verification of the climate proofing documentation as regards climate adaptation, if such a verification is available.

A **Climate Change Vulnerability and Risk Assessment** (CCVRA) of the project has been carried out by CDP Risk Management, in collaboration with an independent auditor, to meet the requirements for Kedrion S.p.A.'s financing request from Cassa Depositi e Prestiti (CDP), backed by an EU InvestEU guarantee. The funds from this financing will be directed towards supporting a portion of Kedrion's financial needs for upcoming investments in Italy, scheduled between 2024 and 2027, as detailed in the company's 2023-2029 Economic and Financial Plan. These investments aim to strengthen Kedrion's innovation and development efforts, ensuring continued growth and sustainability in the years to come.

The assessment has been conducted in compliance with the European Commission's "Technical Guidance on Climate-Proofing of Infrastructure Projects for the Period 2021-2027," ensuring the project's resilience to climate change impacts. In line with these guidelines, the assessment has been divided into two phases:

- Screening (Phase 1): This phase evaluates the project's vulnerability to climate change.
- Risk assessment (Phase 2): For any risks identified as significant (i.e., medium-high and extreme risks), further evaluation and consideration of relevant adaptation measures were undertaken.

The projects aim to enhance technological competitiveness across various sectors and regions, while also fostering employment opportunities.

The key projects include: Project 1 (development of a new 10% IgG preparation, free of isoagglutinins); Project 2 (development of a plasmaderived Factor V concentrate for the treatment of parahemophilia); Project 3 (new therapies for rare diseases utilizing previously unused plasma fractionation intermediates); Project 4: (development of a new 10% immunoglobulin preparation for intravenous use, incorporating triple inactivation). Each project has specific realization objectives and a well-defined location. Overall, the four projects subject to the funding request will take place at the following Kedrion facilities:

• Site in Sant'Antimo, Naples, Campania Region

- Site in Bolognana, Lucca, Tuscany Region
- Site in Barga (Frazione Castelvecchio), Lucca, Tuscany Region

Thus, the analysis will cover the effects of climate-related hazards on these facilities.

In **Phase 1** (Screening phase), the key elements of the project were, including the pharmaceutical laboratory infrastructure, essential equipment, and the operation and maintenance aspects, such as cleanroom facilities, environmental control systems (HVAC, temperature, humidity), power supply systems, physical security measures, fire suppression systems, and storage and waste management protocols. This phase also aimed to pinpoint potential climate-related risks that could affect the long-term performance of the infrastructure. The risks considered were those outlined in the Delegated Act 2021/2139, Annex 1, Appendix A (European Commission, 2021). To this end, the analysis has been based on the IPCC guidelines and the Climate Change Knowledge Portal (CCKP) for gathering both current and future climate data. Additionally, relevant resources ave been utilized, including NASA's Sea Level Projection Tool and the World Resources Institute's Aqueduct, to evaluate future sea-level rise and assess Water Stress levels respectively.

Given the Kedrion's location, the assessment considered the following list of chronic and acute variables:

- Temperature related: Heat Stress, Temperature Variability, Heat waves, Changing Temperature, Wildfire (Barga and Bolognana);
- Water related: Drought, Changing precipitation patterns and types, Heavy Precipitation, Flood (Barga and Bolognana);
- Mass related: Landslide (Barga and Bolognana)

Notably, since the Barga and Bolognana sites are in close proximity, they can share similar climate hazards, thus risks and vulnerabilities.

In **Phase 2** (Risk Assessment phase), a comprehensive analysis of the climate-related hazards identified in Phase 1 was conducted. The likelihood of each event occurring was evaluated, along with their potential impacts on assets, the environment, and social, financial, and reputational factors. By combining the analyses of likelihood and impact, hazards with extreme risk levels were identified, including Water Stress and Heavy Precipitation for all sites, and Drought specifically for the Sant'Antimo sites.

Hazards classified as **high risk** include Landslide, Flood, Wildfire, and Drought (limited to the Barga and Bolognana sites), while **medium risk** is associated with Temperature Variability and Changing Precipitation Patterns.

Considering the results of the risk assessment, a thorough analysis of the technical documents provided by the project client was conducted.

Additionally, questionnaires were distributed to the client's technical team to gather insights on the adaptation measures incorporated into the project. The key takeaways are summarized below:

- To mitigate temperature-related risks, such as heat waves, heat stress and changing temperature pattern, as stated by Kedrion, the structures are equipped with insulation capable of maintaining temperature gradients that ensure the efficiency of both equipment and production processes. Where temperature limits are defined by GMP standards, these are safeguarded by redundant systems designed to withstand extreme external temperatures. Moreover, the most critical equipment requiring specific temperature control are located in dedicated temperature-regulated areas (e.g., data centers, electrical cabins, UPS units, etc.), in which specific regulation are implemented.
- To mitigate risks associated with water-related risk such as heavy precipitation events and flood, the site in Bolognana has been located in a position that ensures natural drainage of stormwater. Moreover Kedrion sites have developed a comprehensive stormwater management and drainage system which is in place to effectively collect and channel rainwater away from the facility in a timely manner. In the event of local flooding within certain areas, an emergency response procedure has been established, for Sant'Antimo Site, including external pumping systems for quick water removal.

Nevertheless to mitigate risks associated with urban flooding and runoff, exacerbated by heavy rainfall, all the sites have implemented several adaptive measures. A surface water management system has been designed, including both impermeable and permeable areas. The impermeable sections, such as asphalted and cemented areas, are equipped with drainage systems that efficiently collect and divert stormwater. The permeable sections, consisting of natural soil, ensure water infiltration, thereby reducing runoff. Additionally, the site is equipped with an extensive system of surface drains and underground channels, made of cement or PVC, which have been oversized based on local rainfall data to handle peak precipitation events. These measures ensure effective water management, preventing local flooding and protecting the facility's operations during periods of intense rainfall.

• To mitigate risks associated with water stress, the site has implemented several adaptive measures. The facilities in Naples and Bolognana benefit from a dual water supply system, consisting of a well and a public water network, which account for 60% and 40% of water use, respectively. At the Barga facility, water is currently supplied by the public aqueduct, with a well under construction pending authorization. This redundancy ensures that, in the event of a disruption in one source, the other can continue to meet the site's operational water needs.

- Additionally, a storage reservoir is available, the facility in Lucca province features a rainwater collection system that gathers water from the rooftops of certain buildings, further reducing reliance on external water sources and to compensate for short periods of water scarcity a drought. These combined measures significantly enhance the site's resilience to water shortages, ensuring continued operational stability even during droughts or periods of limited water availability. It is recommended to implement further adaptation measures for future droughts, such as rainwater collection systems and water-saving fixtures, particularly for the Naples site, which is more exposed to extreme drought events.
- Landslides are generally classified as geological hazards and are not directly linked to climate change. Instead, they are influenced by factors such as geological conditions, slope steepness, soil properties, and land use. However, climate change can indirectly impact landslide risk by altering precipitation patterns and increasing both the intensity and frequency of rainfall. This risk has been specifically evaluated for the sites in the Lucca province, as these facilities are located near areas prone to landslides. To mitigate the risks associated with landslides in Barga, recent interventions have included consolidation works on the slopes above the site and containment measures designed to prevent potential landslide activity. It is recommended to implement actions also for the site in Bolognana weather is required.
- Due to the surrounding wooded areas in Barga and Bolognana, the sites are vulnerable to wildfires. Furthermore, Copernicus data from the EFFIS Wildfire Risk Viewer indicates that these areas are at risk, making it a key consideration in this analysis. According to Kedrion, certain factors, such as riverbeds and barriers, could potentially mitigate the consequences of a wildfire. It is advisable to implement additional preventive measures, including the establishment of firebreaks, regular maintenance of vegetation, and community awareness programs to enhance preparedness and response strategies. These initiatives can significantly reduce the likelihood of wildfires and minimize their impact on the sites.
- Although the risks associated with wind-related events have been assessed as low, it is important to note that storms and high wind speeds, along with other wind-related hazards, pose significant natural risks to many countries across Europe, with a high likelihood of increase according to the IPCC. The Kedrion site appears well-prepared for such events due to its geographical location, situated in an area with moderate risk due to the surrounding terrain. The structures in the intervention area are primarily made of masonry and concrete, with roofs designed to withstand medium to high-intensity winds.

The implemented measures are deemed sufficient and residual climaterelated risk are considered acceptable. We could thus confirm that the

	adaptation measures in the project are adequate and in line with the climate risk identified.
Climate mitigation (proofing), as applicable	Confirm the use of the 'Technical guidance on climate proofing of infrastructure in the period 2021-2027' for the infrastructure projects.
	Provide a comparison of the project type with table 1 in chapter 2.2.5.1 of the sustainability proofing guidance.  Describe the basis for undertaking the proofing.  Describe the quantification of GHG emissions.  Indicate absolute and relative emissions, and compare with the thresholds in chapter 2.2.5.1 of the sustainability proofing guidance.  Describe the basis for undertaking (or not) the monetisation of GHG emissions and identification of low-carbon options.  Indicate expected lifespan of the infrastructure.  For infrastructure with lifespan beyond 2050, describe its compatibility with conditions of climate neutrality as regards O&M and decommissioning.  Verification:  Describe the independent verification of the climate proofing documentation as regards climate mitigation, if such a verification is available.  Not applicable, since the findings of the climate screening process did not
Voluntary measures (Positive agenda checklist)	reveal the need to continue with the proofing phase.  Present the voluntary measures taken to improve the climate performance of the operation, if applicable.
	Not Applicable
Environmental Dimension	
Legal framework	Applicable environmental legislation and compliance of the operation, such as:  - EIA procedures results (e.g. EIA required, EIA screening decision with or without mitigation measures) or any other relevant assessment/s.  -other relevant procedures in the context of the legal compliance process described in chapter 2.3.2 of the sustainability proofing guidance, as applicable to the project.  - permits in place or in progress.  - short information whether a project is consistent with a planning framework (i.e. whether it results from a plan/programme that was subject to a strategic environmental assessment).  Based on the information provided by the Final Recipient and on the requirements set by the Concession Agreement, the project shall comply, among others, with the following legislations: SWD (2030) 55 final and Directive 2010/75/EU - Directive on Industrial Emissions (IED).
Environment dimension (screening)	Describe the conclusions of the InvestEU screening performed based on Checklist 1 in Annex 3 of the sustainability proofing guidance. (For

	example, provide a short justification for why: (i) it is considered that the project has no impact/s or only low impact/s on the elements of the natural capital and the two crosscutting themes; (ii) the project requires an EIA, but no significant residual impacts were identified).  The project was screened against the criteria detailed in the Checklist in Appendix 3 of the Sustainability Proofing Guidance. The project is unlikely to generate negative impacts on any of the environmental elements (air, water, land and soil, biodiversity, noise, and odour).  The project is located at the company's production sites, which comply with IPPC regulations, have already obtained Integrated Environmental Authorization (IEA), and meet EMAS standards while adhering to the Best Available Techniques (BAT).  As a Research and Development activity, the operation doesn't fall under the annexes of Directive 2011/92/EU (amended by Directive 2014/52/EU) on Environmental Impact Assessments (EIA) and is therefore not subject to a mandatory EIA.
Environment dimension (proofing), as applicable	Describe the basis for undertaking the proofing (results of the screening). Describe the identified impacts.  Describe proposed mitigation and/or compensation measures (and their costs).  Quantification and monetisation of the residual risks, where applicable Justify why residual risks are acceptable.  Not applicable, since the findings of the environmental screening process did not reveal the need to continue with the proofing phase.
Voluntary measures (Positive agenda checklist)	Present the voluntary measures taken to improve the environmental performance of the operation, if applicable.  The implementation of the proposed project can generate several positive environmental impacts. Indeed, among the major aims of the Kedrion's project there is to:  • Construct a new ethanol distillation and storage plant, along with a system for collecting and storing recovered hydroalcoholic solution (mother liquors).  • Reintroduce special industrial waste (unused plasma processing intermediates) into the production cycle.  It is important to mention the certifications obtained by the company, such as ISO 14001 and SA7999, as they demonstrate the company's commitment to environmental management and social responsibility.
Social Dimension	
Legal framework	Applicable labour and social legislation and compliance of the operation. Based on the information provided by the Final Recipient and on the requirements set by the Concession Agreement, the project shall comply, among others, with the Directive 89/391/EEC on the protection of workers' health and safety in industrial sectors, including pharmaceutical production sites.

Social dimension (screening)	Describe the results of the InvestEU screening performed based on the Checklist in Annex 3 of the sustainability proofing guidance. (For example, provide a short justification why it is considered that the project has no impact/s or only low impact/s on the dimension of criteria of the social dimension described in Chapter 2.4 of the sustainability proofing guidance).  The project was screened against the criteria detailed in the Checklist in Appendix 3 of the Sustainability Proofing Guidance. The project is unlikely to generate negative impacts on the various issues outlined in the social dimension.
Social dimension (proofing), as applicable	Describe the basis for undertaking the proofing (screening results).  Describe the identified impacts.  Describe proposed mitigation and compensation measures.  Describe residual risks and justify why they are acceptable.  Not applicable, since the findings of the social screening process did not reveal the need to continue with the proofing phase.
Voluntary measures (Positive agenda checklist)	Present the voluntary measures taken to improve the social performance of the operation, if applicable. Explain any other positive social impact expected from the operation, regarding, in particular: i. Gender equality and women's empowerment; ii. Social inclusion and, iii. Resilience building.  The implementation of the proposed project can generate several positive social impacts contributing to support vulnerable groups and fostering gender equality. Project is expected to recruit women and under 36 employees.  The project is based on sites compliant with the ISO 45001 standard for "Occupational Health and Safety Management System" and BS OHSAS 18001 (Occupational Health and Safety Management System).
Other sustainability aspects (	as applicable)
	Public consultations (part of EIA, on a voluntary basis etc.).  Consultation with interested parties (in cases of relocation of people, expropriations or otherwise significant impacts on living conditions).  Specific mitigation measures (in cases of, e.g. impacts on heritage, urban planning, etc.).  Capacity of the project promoter/final recipient.  Specific contractual arrangements.  Specific monitoring and reporting requirements.  Synergies across dimensions, where possible.  Not applicable.