Questions and Answers No. 1

Within the framework of the tender procedure for the Supply of Medical Equipment and Ambulance Vehicles within the framework of the Cross-Border Cooperation Programme INTERREG IPA "Greece – North Macedonia 2021-2027"

Reference number: Heart Safe - 24617 – 04

Q1.	**Request for amendment of the technical specifications – PUBLICATION** On behalf of Avtomobilska Grupa DOOEL, official and general importer of Renault vehicles in North Macedonia, we would like to express our interest in participating in the tender procedure under reference: HEART SAFE CBA – 24617 – 04 regarding the procurement of ambulances. After analyzing the published technical specifications, we have remarks regarding certain requirements that may unintentionally restrict fair competition. In particular, the requirement for a minimum engine displacement of 2100 cm^3 is a limiting criterion. Renault ambulances, which constitute a significant part – approximately 90% – of the ambulance fleet in North Macedonia, are equipped with 1997 cm^3 engines, and yet fully meet all the operational, performance, safety and efficiency requirements for “medical transport”. In this context, such a specification excludes Renault vehicles from participation, thus placing us, as their official importer, in a disadvantageous and discriminatory position. In the interest of ensuring fair competition, wider participation and optimal value for the contracting authority, we request a revision of the technical requirement	**A1**	We inform you that the contracting authority will continue to revise and appropriately harmonize the technical specification related to the engine displacement, in order to ensure greater competitiveness and equal access for economic operators in the procedure. In this regard, the technical requirement will be amended to allow a minimum engine capacity of approximately 2000 cm^3, i.e. vehicles with a displacement of 1995 cm^3 will also be acceptable, provided that they meet the other technical and functional requirements provided for in the tender documentation.

	related to the engine working area. We propose that the specification be adjusted to allow vehicles with an engine displacement of a minimum of 1995 cm3 (approximately 2000 cm^3), provided that all other performance and functionality criteria are met. Such a change will not compromise the quality or functionality of the ambulances, but will instead promote inclusiveness and allow reputable suppliers, including us, to submit competitive bids. We remain at your disposal for any further clarifications and would be grateful if you would consider this request. Thank you for your understanding.		
Q2	Following a detailed review of the published technical specifications for the procurement (PUBLICATION REF.: HEART SAFE CBA-24617-04) of mobile public access defibrillators (fully automatic and semi-automatic Part2 and Part3), as well as the ECG device (Part 4) , we would like to respectfully raise several concerns regarding certain requirements that may unintentionally limit fair competition among economic operators. We have identified a number of elements within the specifications that appear overly prestrictive and potentially aligned with a specific manufacturer's design approach, rather than based on essential functional and clinical performance. These include, but are not limited to: Requirement for RFID tags for pad shelf-life monitoring Automatic recognition of electrode	**A2**	Following your observations, we respectfully maintain that the requirements specified are essential to ensuring safety, reliability, and clinical effectiveness. Below is a point-by-point explanation: - Requirement for RFID tags for pad shelf-life monitoring This is critical for patient safety. Pads degrade over time, and RFID ensures automated, accurate monitoring without reliance on manual checks, reducing risk of expired consumables and inability of defibrilation in case of emergencies. - Automatic recognition of electrode type with energy adjustment This feature guarantees correct shock delivery regardless of electrode type, minimizing human error and ensuring optimal therapy. It is a safeguard against misuse in high-stress scenarios.

	type with energy adjustment Obligation for integrated SD card storage Strict specification of Li-MnO_2 battery type with defined voltage Defined Myogram filter options (LP 25, LP 40 or LP 150, 150 Hz or Off (250 Hz)) Requirement for QT interval must have the use of at least the following Bazett, Fredericia, Framingham and Hodges While we fully recognize the importance of ensuring high-quality and reliable medical equipment, such narrowly defined criteria may exclude other internationally recognized manufacturers whose devices meet equivalent or superior clinical and safety standards, while utilizing different technical solutions. In this regard, we kindly propose that these specifications be revised to focus on performance-based and clinically relevant requirements, rather than specific technical implementations. For example: Allow alternative methods for pad shelf-life monitoring (not limited to RFID) Accept both automatic and manual pediatric/adult mode selection, provided safety is ensured Permit different data storage solutions (internal memory, USB export, etc.) instead of strictly requiring an SD card Broaden battery requirements to include equivalent or superior technologies that meet autonomy and performance criteria		- Obligation for integrated SD card storage Integrated storage provides secure, tamper-proof recording of event data, which is vital for clinical review, legal documentation, and quality assurance. External or optional storage solutions risk data loss or incompatibility. - Strict specification of Li-MnO_2 battery type with defined voltage Li-MnO_2 battery type is standard of the mjor high quality manufacturers and voltage specification ensures long shelf-life, reliability in extreme conditions, and predictable performance. Alternative battery types may compromise readiness or require more frequent replacement. - Defined Myogram filter options (LP 25, LP 40 or LP 150, 150 Hz or Off (250 Hz)) Standardized filter options are necessary for consistent ECG interpretation across devices. This avoids variability that could mislead clinicians and ensures compatibility with established diagnostic protocols. All well-known manufacturers use the same filters and this condition is not restrictive - Requirement for QT interval must have the use of at least Bazett, Fredericia, Framingham, and Hodges Multiple correction formulas are required because QT interval assessment varies with heart rate. Providing all four ensures clinicians can select the most appropriate method, supporting accurate diagnosis and treatment. These formulas are widely recognized internationally and

	Allow flexibility in ECG filtering options, provided clinically acceptable performance is ensured Remove the mandatory requirement for the Bazett method in QT correction, and allow equivalent clinically validated formulas (e.g. Fredericia, Framingham, Hodges) Adopting a more open and performance-based approach would: Encourage broader participation from multiple qualified manufacturers Enhance competition and transparency Potentially result in more economically advantageous offers Ensure alignment with principles of fair and non-discriminatory public procurement We would appreciate your response within the clarification period and confirmation whether the above points will be reflected in an amendment to the tender dossier. We remain at your disposal for any further clarification or technical discussion and would be pleased to contribute constructively.		are standard options in modern ECG interpretation systems. While we understand concerns about competition, these requirements are not eliminatory nor aligned with a single manufacturer. They are defined to guarantee clinical safety, interoperability, and reliability in life-critical situations. Reducing these standards would weaken the assurance of device performance and compromising patient outcomes.