

Government of India Department of Space HUMAN SPACE FLIGHT CENTRE Bengaluru – 560 094 Phone: +91-080-2217 2675/79, Email: smitha-hsfc@isro.gov.in

संदर्भ सं./Ref No: HSFC/Eol/01/2023

15 फरवरी/February 15, 2023

"पहनने योग्य स्वास्थ्य मानीटरन प्रणाली के स्वदेशी विकास हेतु विक्रेताओं की पूर्व अर्हता के लिए अभिरुचि की अभिव्यक्ति" का आमंत्रण

INVITATION FOR "EXPRESSION OF INTEREST FOR PRE-QUALIFICATION OF VENDORS FOR DEVELOPMENT OF INDIGENOUS WEARABLE HEALTH MONITORING SYSTEM"

समानव अंतरिक्ष उड़ान केंद्र [एच.एस.एफ.सी., इसरो], भारत सरकार "पहनने योग्य स्वास्थ्य मानीटरन प्रणाली के स्वदेशी विकास हेतु विक्रेताओं की पूर्व अर्हता के लिए अभिरुचि की अभिव्यक्ति"को आमंत्रित करता है । इसका संक्षिप्त विवरण इसरो की वेबसइट www.isro.gov.in पर 'निविदा' के तहत उपलब्ध है ।

Human Spaceflight Centre **[HSFC, ISRO]**, **Government of India invites Expression of Interest for pre-qualification of Vendors for development of indigenous wearable health monitoring system.**" Brief Specification is available in the ISRO website <u>www.isro.gov.in</u> under <u>'Tenders'</u>.

इच्छुक विक्रेता जिनके पास पर्याप्त जानकारी, अनुभव, अपेक्षित सुविधाएं और जो वित्तीय रूप से समृद्ध हैं, को, अपनी अभिरुचि की अभिव्यक्ति हस्ताक्षरित एवं मुहरबंद लिफाफे में एच.एस.एफ.सी., बेंगलूरु में जमा कराने के लिए आमंत्रित किया जाता है ।

Interested Vendors having sufficient know-how, experience, required facilities and financial background are invited to express their interest to submit their signed and sealed Envelope to HSFC, Bengaluru.

अभिरुचि की अभिव्यक्ति" के साथ कृपया ब्यौरेवार निम्नलिखित सूचना भी प्रस्तुत करें

Along with "Expression of Interest" please furnish the following information also in detail:

1	दूरभाष, फैक्स, ई-मेल, वेब इत्यादि सहित पंजीकृत पता Registered address with Phone, Fax, Email, Web etc.	8	परियोजना विकास से संबंधित प्रत्येक क्षेत्र में विशेषज्ञता प्राप्त मानवशक्ति का विवरण Details of Specialized Manpower in each area related to the Project Development
2	स्वामी, भागीदार, निदेशक मंडल इत्यादि के नाम और पते के साथ कंपनी की स्थिति (स्वामित्व/भागीदारी/निजी निगमित आदि) Company Status (Proprietary / Partnership / Private Ltd. Etc.) with Name and Address of Proprietor, Partners, Board of Directors etc.	9	वित्तीय क्षमता / उपलब्ध ऋण सुविधा Financial Capacity / Credit facilities available
3	सहयोगी: (क) भारतीय (ख) विदेशी Associates: (a) Indian (b) Foreign	10	संस्थान का वस्तु एवं सेवा कर पंजीकरण संख्या, पैन संख्या, आई.एस.ओ. प्रमाणन या उसके समकक्ष Establishment's Goods Service Tax Registration Number, PAN Number, ISO Certification or equivalent
4	पूरे पते एवं संपर्क व्यक्तियों के साथ प्रमुख ग्राहकों की सूची List of Major Customers with full address and their Contact Persons	11	व्यापार संघ जिससे आप संबद्ध हैं Trade Association to which you belong to
5	अन्य संविदाएं, यदि फिलहाल कोई हैं, के विवरण/Details of other Contracts, if any now in hand	12	बैंकर के नाम एवं पता Name and Address of the Bankers

6	अपने स्वामित्व/ पास उपलब्ध अवसंरचना सुविधाओं के विवरण Details of Infrastructure Facilities owned / available	13	व्यापार की प्रकृति Nature of Business
7	पूंजी तथा गत तीन वर्षों का टर्नोवर साथ ही नवीनतम वार्षिक रिपोर्ट की प्रति Capital and Turnover for last Three years with copy of latest Annual Report	14	अन्य कोई सूचना जिसे आप संबद्ध समझें Any other information you consider relevant

नोट/Note:-मेक इन इंडिया नीति के अनुसार, श्रेणी-। तथा श्रेणी-।। के स्थानीय आपूर्तिकर्ता इस बोली में भाग लेने हेतु पात्र हैं।/ Only Class-I and Class-II Local suppliers as per Make in India policy are eligible to participate in the bid

उपरोक्त सूचना के साथ आपकी अभिरुचि की अभिव्यक्ति निम्नलिखित पते पर भेजी जाए जिसके लिफाफे पर दिनांक 31.03.2023 की ई.ओ.आई. संख्या HSFC/ADVT/01/2023 अंकित हो । ई.ओ.आई. जमा कराने की अंतिम तारीख <u>31 मार्च 2023 14.00 बजे है (भारतीय मानक समय) ।</u>

The Expression of Interest with all the above information should reach the following address superscribing the envelope as EoI No: HSFC/ADVT/01/2023 dated 31.03.2023. The Due Date for submission of EoI is <u>March 31, 2023 at 14.00 Hours IST</u>.

क्रय एवं भंडार अधिकारी/Purchase & Stores Officer, समानव अंतरिक्ष उड़ान केंद्र/Human Space Flight Centre, इसरो मुख्यालय परिसर/ISRO HQ Campus, न्यू बी.ई.एल.रोड/New BEL Road, अंतरिक्ष भवन/Anthariksh Bhavan, बेंगलूरु/Bengaluru – 560 094

ई.ओ.आई. के लिफाफे पर "भेजने वाले" का पता और एच.एस.एफ.सी. की संदर्भ संख्या अंकित की जानी चाहिए। किसी भी स्पष्टीकरण के लिए कृपया +91-080-2217 2675/79 तथा ई-मेल <u>smitha-hsfc@isro.gov.in</u>. पर हमसे संपर्क कर सकते हैं । अंतिम तारीख और समय के बाद प्राप्त ई.ओ.आई. पर मूल्यांकन हेतु विचार नहीं किया जाएगा । एच.एस.एफ.सी. के पास बिना कारण बताए सभी या किसी ऐसी अभिरुचि की अभिव्यक्ति को स्वीकार करने या अस्वीकार करने का अधिकार है ।

The Eol cover should indicate "SENDERS" Address and HSFC Reference Number. For any clarification you may please contact us on +91-080-2217 2675/79 and email ID <u>smitha-hsfc@isro.gov.in</u>. Eol received after due date and time will not be considered for evaluation. HSFC reserves the right to accept or reject all or any such "Expression of Interest"; without assigning any reasons what so ever.

हस्ता/Sd/-व.क्रय एवं भंडार अधिकारी Sr. Purchase & Stores Officer

Expression of Interest for prequalification of parties for indigenous development of Wearable Health Monitoring System

1. Background

As part of Gaganyaan Program which is India's Human spaceflight project, HSFC requires development of wearable health devices specifically to measure physiological stresses on human body due to intense physical exertion. In addition, wearable medical devices are also required to study the physiological condition response as well as measurement of sleep quality. These devices must be comparable to similar clinical grade medical equipment used under ambulatory care settings.

The purpose of this EOI is to assess the profile and technical capability of India-registered enterprises including start-ups (DPIIT registered) for development of research grade wearable health monitoring systems and associated analytics.

The enterprise profile and technical capability will be used to prequalifyenterprises which fulfil the selection criterion (given in Section 4) for the following activities:

- End to end design and development of wearable health monitoring system which includes associated hardware, software, data storage and transmission using wired/ wireless medium to private cloud/storage device along with integrated health data analytical engine with appropriate GUI
- Limited field trials for system validation
- Certification compliance with
 - $\circ\,$ ISO 10993 (or equivalent) for biocompatibility
 - $\circ\,$ IEC 60601 (or equivalent), for electrical safety standards
 - $\,\circ\,$ CDSCO/ FDA/CE (or equivalent) for manufacture and clinical investigation
- Training, maintenance and support for the proposed solution along with comprehensive documentation

Upon completion of the pre-qualification evaluation, HSFC, ISRO will include the selected parties in a roster of pre-qualified developers of wearable health monitoring system who may directly be invited to submit technical and financial bids in response to upcoming *Request for Proposal (RFP)* for development of the same. The RFP will contain detailed technical requirements and schedule.

2. System Requirements

The proposed wearable health monitoring system would be a multi-functional system that would provide real-time health monitoring data to users. The device would be worn by the user and accountable to collect and transmit data either to an internal storage, or to a dedicated system via wired interface or wirelessly. It should be noted that in case of wireless transmission, the data must be stored on a private cloud in the premise of ISRO.

The EOI aims for the development of three models of wearable system with capability to acquire research-grade/ medical-grade physiological data non-obtrusively and non-invasivelyfor monitoringday-to-day activities of the subject. The EOI accepts solution for either of the models, or multiple of them, or may incorporate all functionalities in an individual system, as much as feasible without compromising any requirements. The details of the models are as follows:

Criterion	Model-1	Model-2	Model-3	
Intended use	Internal load monitoring during physical training comprising of treadmill, cycling, swimming, weight training, circuit training, etc.	Health monitoring under controlled environment, majorly intended for various physiological conditioning studies	Post-training recovery assessment including sleep monitoring and brain activity	
System form & portability	Completely wearable	DAQ module and wea	rable sensors	
Heart function	Monitor heart rate & heart rate (HRV)	ECG with arrhythmia detection capability (3-lead ECG or higher) 3-lead ECG or hig		
Brain activity	No	No	Yes, 6-lead EEG with sleep quality indicator, REM & N- REM stages	
Blood pressure	No	Non-invasive & Desired		
Skin temperature	Yes		Desired	
Respiratory rate	Desired	Y	es	
SpO2	Yes			
Data transfer	Every 5 seconds or faster			
Data storage	> 100 MB device storage or transfer to private cloud			
Interface	Wired/ wireless			
Biocompatibility	Y Yes			
Electronic Components	COTS equivalent			

3. Submission Requirements

3.1	Enterprise profile	Details to be furnished
Α	Business entities involved in	Company name & address
	development, sales and	 Business Registration details
	marketing of wearable health	Product & services portfolio
	monitoring devices	 Details of users/clients
		 Last three years' financial statement
		 MSME category based on investment &
		turnover
		 Details of in-house human resource
		 Details of collaborations – if any
В	Start-ups (DPIIT registered)	Company name & address
	involved in development, sales	DPIIT Registration details
	and marketing of wearable	Profile of founder members and leads
	health monitoring devices	 Products& services portfolio
		 Funding stage&Valuation details
		 Details of in-house human resource
		 Details of collaborations – if any
3.2	Technical capability	Details to be furnished
A	Business entities involved in	 Details of prior experience in design,
	development, sales and	development and qualification of medical
	marketing of wearable health	devices (wearable/ non-wearable)
	monitoring devices	 Details of in-house design, qualification and
		manufacturing facilities
		Certification compliance and details
В	Start-ups (DPIIT registered)	 Details of product development in
	involved in development, sales	wearable/non-wearable medical devices
	and marketing of wearable	Details of benchmarking the device with
	health monitoring devices	standard medical equipment
		Details of in-house technical expertise and
		facilities
3.3	Brief description of proposed	For existing device which meets major
	solution	requirement: Brief description of solution
		including hardware & software
		For a device which is under development - brief description of development status and
		brief description of development status and further plans
		further plans
		For new device development – brief description of technology and validation
		description of technology and validation challenges
<u> </u>		Chanenges

The EOI with all applicable documents must be submitted in a sealed envelope indicating "SENDERS" address and HSFC Reference Number to following address:

Purchase & Stores Officer, Human Space Flight Centre, ISRO HQ Campus, New BEL Road, Anthariksh Bhavan, Bengaluru – 560094

The due date for submission of EoI is **March31, 2023 at 14.00 Hours IST.** For any clarification you may please contact us on <u>080 22172675/79</u> or email ID smitha-hsfc@isro.gov.in. EOI received after due date and time will not be considered for evaluation.

4. Methodology for pre-qualification and selection criteria

The evaluation criteria to pre-qualify enterprises participating in the EOI is tabulated below according to the Evaluation Criteria Number (ECN):

		Score	
ECN	Evaluation Criteria	Business entities	Start- ups
4.1.	Enterprise profile		
4.1.1.	Company name & address with business registrationdetails	5	5
4.1.2.	Products & services portfolio	10	10
4.1.3.	Last three years' financial statement	10	NA
4.1.4.	DPIIT registration details, profile of founding members and leads	NA	10
4.1.5.	Details of users/clients and collaborations	5	5
	Sub-total	3	0
4.2.	4.2. Technical capability		
4.2.1.	Prior experience in design, development and qualification of wearable/ non-wearable medical devices	10	NA
4.2.2.	Existing product in wearable/non-wearable health monitoring segment	NA	10
4.2.3.	Design documentation of developed/underdevelopment product	20	20
4.2.4.	Certification compliance and details	5	NA
4.2.5.	Benchmarking the device with standard medical equipment	NA	5
4.2.6.	Adequacy of in-house technical resources for design and development	5	5
	Sub-total 40		
4.3.	Brief description of proposed solution		
4.3.1.	System configuration for Model-1	10	10
4.3.2.	System configuration for Model-2	10	10

4.3.3.	4.3.3. System configuration for Model-3		10
Sub-total		3	0
<u>Total Maximum Score</u>		1	00
	Minimum score for pre-qualification		0

The table below draws the scheme for evaluation criteria, referring the Evaluation Criteria Number (ECN) from above table:

ECN	Scoring Scheme	Remarks
4.1.1.	 Score of 5 rewarded, if all details are furnished 	Non-submission of details will lead to disqualification
4.1.2.	 Score of 10 rewarded, if portfolio comprises of clinical- grade or research-grade medicaldevices Score of 5 rewarded, if portfolio comprises ofconsumer-grade medical devices 	Portfolio not fitting in medical domain will lead to disqualification
4.1.3.	 Score of 10 rewarded, if financial statement is audited by third-party Score of 5 rewarded, if financial statement is internally audited Score of 10 rewarded, if all details are furnished 	Non-submission of details will lead to disqualification
4.1.4. 4.1.5.	 Score of 5 rewarded, if details furnished Score of 0 rewarded, in either case 	
4.2.1.	 Score of 4 rewarded, if experienced in design & development Score of 3 rewarded, if experienced in manufacturing Score of 3 rewarded, if experienced in qualification Score will be a sum of all three aspects mentioned 	
4.2.2.	 Score of 10 rewarded, if product is developed andcommercially available Score of 7 rewarded, if product is developed & under limited trial Score of 3 rewarded, if product is under development 	
4.2.3.	Scoring will be on the discretion of RFPevaluationpanel based on design concept, hardware configuration, software architecture, test plan and user manual	Non-submission of details will lead to disqualification
4.2.4.	 Score of 5 rewarded, if details are furnished Score of 0 rewarded, in either case 	
4.2.5.	 Score of 5 rewarded, if details are furnished Score of 0 rewarded, in either case 	
4.2.6.	 Score of 5 rewarded, if all details are furnished Score of 0 rewarded, in either case 	

4.3.1.	Scoring will be on the discretion of RFP evaluationpanel,	Minimum
	under the metrics including but not limited to design	submission of one
_	concept technical constraint bardware configuration	configuration model
4.3.3.	software architecture and test plan	is required for
	Software architecture and test plan	qualification

5. Disclaimer

- 5.1. This EOI does not entail any commitment on the part of HSFC, ISRO or any other participating ISRO agencies, either financial or otherwise. HSFC, ISRO reserves the right to accept or reject any or all EOIwithout incurring any obligation to inform the affected supplier/s of the grounds.
- 5.2. Requests for Proposal (RFP) and any subsequent purchase order (PO) will be issued in accordancewith the rule and procedures of HSFC, ISRO and other participating ISROagencies.

6. Glossary of Terms

EOI	Expression of Interest
RFP	Request for Proposal
РО	Purchase Order
HSFC	Human Space Flight Centre
Start-up	As defined by Ministry of Commerce and Industry, Government of India
DPIIT Department for Promotion of industry and Internal Trade	
ECG	Electrocardiogram
HRV	Heart Rate Variability
СОТЅ	Commercial off-the-shelf