# REQUEST FOR PROPOSAL (RFP) – PE005

## Title: Call for manufacturers of design-locked automated or semi-automated upper arm cuff blood pressure measuring devices for home-based monitoring in pregnancy

**RFP Number:** RFP-PE005-SECURE

**Issue Date:** 18 August 2026

**Closing Date:** 15 September 2026 at 23:59 (UTC)

**Email address for questions & submissions:**
secure.rfp@auruminstitute.org

## Glossary of Terms and Abbreviations

| Term / Abbreviation | Definition |
|---|---|
| **ANC** | Antenatal care. |
| **BHS** | British Hypertension Society; publisher of a blood pressure device validation protocol. |
| **BP** | Blood pressure. |
| **CE marking** | Conformity marking indicating a device meets applicable European Union health, safety, and performance requirements. |
| **CHAI** | Clinton Health Access Initiative; lead of the SUPREME-SECURE consortium. |
| **CHW** | Community health worker (or an equivalent national cadre, e.g. Kenya Community Health Promoters, Tanzania CHWs, Ghana community health nurses). Note: CHW status varies by country |
| **Design lock (design freeze)** | Formal confirmation that a device's design, components, firmware/software, cuff specification, labelling, and manufacturing process are finalised and will not change. |
| **Digital BP measuring tool** | An electronic sphygmomanometer for measuring the force of blood in a patient's arteries, as opposed to a manual auscultatory device. |
| **EMR** | Electronic medical record. |
| **FDA (US)** | United States Food and Drug Administration. |
| **Home-based use** | For this RFP, BP measurement at or near the home by a lay worker (lay user), covering self-monitoring (SMBP), measurement by a lay family member, and measurement by a community health worker (CHW). Used throughout as the umbrella term for the setting. |
| **HMIS / DHIS2** | Health management information system / District Health Information Software 2; national routine health data platforms. |
| **IEC** | International Electrotechnical Commission; publisher of electrical and medical device standards (e.g. IEC 60601 series, IEC 80601-2-30, IEC 62366-1). |
| **IMDRF** | International Medical Device Regulators Forum-a forum of regulators (not itself a regulatory authority). Founding members' regulatory authorities: USA (FDA), European Commission, Japan (PMDA), Canada (Health Canada), Australia (TGA). |
| **IP rating** | Ingress Protection rating indicating resistance to dust and water. |
| **IRP** | Independent Review Panel providing oversight of the SUPREME-SECURE supplier selection process. |
| **ISO** | International Organization for Standardization. |
| **ISO 13485:2016** | Quality management system standard for medical devices. |
| **ISO 14971** | Standard for the application of risk management to medical devices. |
| **ISO 81060-2:2018** | Standard for clinical validation of intermittent automated (cuff-based) non-invasive blood pressure measuring devices, including a pregnancy special-population requirement. |
| **LMIC** | Low- and middle-income country. |
| **MAP** | Mean arterial pressure; an average arterial pressure derived from systolic and diastolic values |
| **NIBP** | Non-invasive blood pressure. |
| **QMS** | Quality management system. |
| **RFP** | Request for Proposals. |
| **SECURE** | **S**ustainable **E**quitable **C**are and **U**niversal **R**esources for **E**clampsia and Anaemia (the project within SUPREME that this RFP sits under). |
| **SMBP** | Self-monitoring of blood pressure: a pregnant woman measures her own BP as a complement to clinic measurement (the WHO evidence base also counts measurement by a lay family member). |
| **SRA** | Stringent Regulatory Authority. |

| Term / Abbreviation | Definition |
|---|---|
| **STRIDE BP** | International scientific initiative that lists validated blood pressure measuring devices. |
| **SUPREME** | **S**ustained **U**ptake of **P**roducts for **P**re-eclampsia and Maternal **A**naemia |
| **TAP** | Target Access Profile: defines optimal product access terms. |
| **The Aurum Institute** | The Aurum Institute NPC, company registration number 1998/009355/08 |
| **TCO** | Total cost of ownership. |
| **TPP** | Target Product Profile: describes the ideal characteristics of a product class. |
| **Unitaid** | Global health agency hosted by the World Health Organization; funder of SUPREME-SECURE. |
| **VDL** | Validated Device Listing (independent listing of validated BP devices). |
| **WHO** | World Health Organization. |
| **WHO PQ** | WHO Prequalification. |
| **WLA** | WHO-Listed Authority: a regulatory authority formally designated by WHO as operating at an advanced, globally recognised level. Note: the WLA framework is designed primarily to facilitate WHO reliance and is not yet an established pathway for non-IVD medical devices such as BP monitors. |

# Section 1: Overview

## 1.1 Objective of this RFP

Under SUPREME-SECURE, the Aurum Institute, in collaboration with the Clinton Health Access Initiative (CHAI), is issuing this open Request for Proposals (RFP) to identify and select up to two suppliers of design-locked automated or semi-automated upper arm cuff blood pressure (BP) measuring devices suitable for home-based use in pregnancy.

The primary objective is to generate clinical validation and operational evidence for selected devices in project countries - including validation in pregnant and pre-eclamptic populations and an assessment of feasibility, acceptability, usability, equity and cost-in order to support regulatory approvals under a lay/community-use intended-use claim and to advance market entry readiness in SUPREME-SECURE project countries. Technical assistance and targeted financial incentives may also be provided to support suppliers in advancing regulatory and market entry readiness.

**Prior validation of the device in a pregnant population is not a requirement to apply.**

This RFP is open to all eligible bidders as defined in Section 5. Eligible bidders include the Legal Manufacturer of an eligible device and Authorised Suppliers acting on the Legal Manufacturer's behalf (both defined in Section 5).

The RFP is posted publicly on the Aurum Institute website and the websites of relevant SUPREME-SECURE consortium partners to ensure equitable access. Manufacturers meeting the eligibility criteria are actively encouraged to apply. Questions are welcome and can be emailed to the dedicated email address for this RFP: secure.rfp@auruminstitute.org.

The product-specific goals of the SUPREME-SECURE BP workstream are to:

- Ensure that reliable, user-friendly BP measuring technologies suitable for home-based use are validated for normotensive and hypertensive (including pre-eclamptic) pregnant women in selected project countries.
- Generate evidence on home-based monitoring in pregnancy - feasibility, acceptability, cost, equity and potential health-system effects-to inform product prioritisation, policy, guideline inclusion, and scale-up; and
- Advance market access strategies for fit-for-purpose, quality-assured devices suitable for home-based use, including registration under an intended use that covers measurement by a lay worker(lay) user.

Specific details on the target product and market context are set out in Sections 3 and 4.

# Section 2: Background and Context

## 2.1 About the SUPREME-SECURE Project

SUPREME (Sustained Uptake of Products for Preeclampsia and Maternal Anaemia) is a Unitaid-funded initiative designed to catalyse equitable access to quality-assured diagnostics and therapeutics for the prevention, diagnosis and management of preeclampsia/eclampsia and maternal anaemia across sub-Saharan Africa. The programme operates across two complementary projects: SUPREME-SECURE and SUPREME-LIFELINES.

SUPREME-SECURE (Sustainable Equitable Care and Universal Resources for Eclampsia and Anaemia) is a four-year project (2026–2029) implemented by a consortium led by CHAI, in partnership with the Aurum Institute, Burnet Institute, Concept Foundation and WACI Health.

The project addresses a critical unmet need: despite the existence of effective, low-cost interventions, preeclampsia and maternal anaemia remain leading drivers of maternal and neonatal mortality in low- and middle-income countries (LMICs), largely due to fragmented markets, weak regulatory systems, poor quality assurance and insufficient supply chain integration.

SUPREME-SECURE operates across four strategic outputs:

- Evidence generation: verification and validation of new diagnostic products, and operational research to inform deployment.
- Demand generation, advocacy, and community and civil society engagement: multi-level stakeholder engagement to build awareness and drive product uptake.
- Product access: market assessments, manufacturer engagement, technical assistance, market shaping and regulatory support to improve the availability of quality-assured products.
- Country adoption and scale-up: country-level market intelligence, product introduction planning, registration support, and catalytic procurement in full and selective implementation countries.

## 2.2 About the Aurum Institute, CHAI, and Unitaid

The Aurum Institute is a proudly African organisation that generates evidence for health policy and translates that policy into practice. We work to accelerate equitable access to urgently needed health products, using our public health programmes to prove what works and drive uptake of proven technologies. Through partnerships, investment, and in-country delivery, we help build stable markets for life-saving commodities globally.

The Clinton Health Access Initiative (CHAI) is a global health organisation committed to catalysing access to high-quality, low-cost drugs and diagnostics and strengthening integrated health systems in resource-limited settings.

Unitaid is a global health agency hosted by the World Health Organization. Unitaid invests in finding innovative solutions to prevent, diagnose and treat diseases more quickly, cheaply, and effectively in LMICs. SUPREME-SECURE is funded by Unitaid under its portfolio on improving access to lifesaving tools for the prevention, diagnosis and management of preeclampsia and maternal anaemia. For more information, please visit www.unitaid.org.

## 2.3 Implementation Countries

SUPREME-SECURE operates in several sub-Saharan African countries, with specific implementation varying by product. For this RFP, the target countries are:

- Ghana (evidence generation country)
- Kenya (evidence generation country)
- Malawi
- Senegal
- Tanzania

In addition to these primary implementation countries, SUPREME-SECURE's market-shaping activities are designed to generate access commitments and regulatory filings that benefit LMICs globally. Bidders are therefore encouraged to consider access pricing, registration strategies and supply commitments that extend beyond the immediate project countries.

## 2.4 Key definitions

A **digital BP measuring tool** is an electronic sphygmomanometer for measuring the force of blood in a patient's arteries, as opposed to a manual auscultatory device. This RFP uses WHO terminology (see the Glossary). Following WHO usage: **self-care** is the ability of individuals, families and communities to promote health and cope with illness with or without a health worker; **self-monitoring of blood pressure (SMBP)** in pregnancy is where the pregnant woman measures her own BP as a complement to clinic measurement (the WHO evidence base also counts measurement by a lay family member). Throughout this RFP, **home-based use** is the umbrella term for the setting in scope: BP measurement at or near the home by a lay worker(lay) user - covering SMBP, measurement by a lay family member, and measurement by a community health worker (CHW). Where the RFP refers to a **lay/community-use intended-use claim**, this means the regulatory intended-use claim covering measurement by a non-professional user.

*Sources: WHO Guideline on Self-Care Interventions for Health and Well-being (2022 revision); WHO Digital Adaptation Kit for Self-Monitoring of Blood Pressure during Pregnancy (2025).*

# Section 3: Product Scope and Market Context

## 3.1 Why home-based monitoring, and the model in scope

Hypertensive disorders of pregnancy -chiefly pre-eclampsia -are among the leading direct causes of maternal death, contributing an estimated 16% of maternal deaths globally.[1] Pre-eclampsia complicates roughly 2–8% of pregnancies, and more than 95% of related maternal and foetal/neonatal deaths occur in LMICs.[2] BP measurement is the most important and most frequent screening test in antenatal care (ANC), and all assessed country guidelines recommend it at every ANC visit. While ANC first contact is near-universal across project countries, continuity is the main gap: fewer than 20% of pregnant women in SUPREME-SECURE countries attend eight or more ANC visits.[3] Pre-eclampsia can develop rapidly between scheduled contacts, so decentralised, home-based monitoring can shorten the interval between a rising blood pressure and clinical action.

WHO's 2022 self-care guideline includes a conditional recommendation supporting SMBP in pregnancy as an additional option alongside clinic-based monitoring. Building on this and informed by a 2026 market assessment and country consultation, SUPREME-SECURE is prioritising the assessment of products for home-based use under the CHW-supported shared-device model described below. *This is the consortium's current assumption of the delivery model; other models for home-based use may be feasible in the medium to longer term, and the details of this model will be refined with countries.*

In the prioritised model:

- A clinician recommends, at an ANC visit, that a woman monitors her blood pressure between ANC visits.
- The woman is linked with a CHW who makes routine home visits and brings a BP device.
- The woman measures her own BP at home, with the CHW available to support device use and interpretation of the result; and
- The CHW records the reading, shares it with the facility, and supports referral where escalation is required.

The device is owned and financed by the health system and shared across a CHW caseload rather than individually purchased. Diagnosis remains a clinical decision based on validated facility measurements; home-based tools have a supportive monitoring role. Bidders should design their proposals around this model.

## 3.2 Technologies in scope and out of scope

Products in scope:

- **Fully automated** upper arm cuff BP measuring devices (electronic, oscillometric, intermittent measurement); and
- **Semi-automated** upper arm cuff BP measuring devices (manual inflation, electronic measurement).

**Products out of scope.** The following technologies are explicitly excluded from this RFP proposal.

| Excluded technology | Rationale for exclusion |
|---|---|
| **Cuffless devices - including smartphone applications estimating BP optically (photoplethysmography) and cuffless wearables** | Consensus clinical evaluation standards for cuffless devices do not yet exist. ISO 81060-2:2018 is scoped to cuffed devices and is not appropriate to the underlying technology of cuffless devices; emerging frameworks (IEEE 1708a-2019; ISO 81060-3:2022; ISO/CD 81060-7 under development; draft FDA guidance on cuffless devices issued January 2026) are not settled. WHO and European Society of Hypertension guidance does not recommend cuffless devices for clinical use, and STRIDE BP does not list them. Evidence generated by SUPREME-SECURE on a cuffless device would be insufficient to ensure patient safety in the absence of such standards against which to assess product performance. The pathway for sustainable uptake is also put at risk by the absence of standards. This exclusion reflects practical constraints of the current RFP round and |

| Excluded technology | Rationale for exclusion |
|---|---|
| | does not represent a permanent position of the consortium on the value of cuffless devices. |
| **Wrist-cuff and finger-cuff devices** | Not included in this RFP. This RFP is scoped to upper-arm cuff devices, which are the form factor with an established validated evidence base, alignment with clinical guidance and country stakeholder preference for facility-referenced measurement, and around which the programme's evidence-generation activities are designed. This exclusion reflects practical constraints of the current RFP round and does not represent a permanent position of the consortium on the value of cuffless devices |
| **Manual auscultatory devices (mercury, aneroid sphygmomanometers)** | This RFP addresses digital (electronic) devices. Manual auscultatory devices are not a priority given the documented access barriers to their use in LMICs including higher costs and difficulty of use. |
| **Facility-grade multiparameter vital-sign monitors and continuous inpatient monitoring systems** | Not fit for the home-based use case that is the target of this RFP. |

## 3.3 Target Product

The table below sets out minimal and optimal characteristics. It distinguishes **eligibility** (what a bidder must have to apply - see Section 5) from the **target product** the supplier should be able to achieve through the RFP. Full requirements, including verification methods, are set out in the Questionnaire (Annex IV).

*The characteristics below describe the ideal product for home-based blood pressure monitoring in pregnancy in the target settings. They are expressed as capabilities required by the population and use case, not as the specifications of any device. Specific values, where given, are indicative; equivalent approaches that meet the underlying need will be considered.*

*These characteristics were informed by the WHO Technical Specifications for Automated Non-Invasive Blood Pressure Measuring Devices with Cuff (2020), together with WHO self-care and self-monitoring of blood pressure (SMBP) guidance. The target product profile extends beyond WHO's procurement-focused specifications to address the specific requirements of monitoring in pregnancy and of a community health worker (CHW)-supported, shared-device model. Applicable performance standards - including ISO 81060-2:2018 (clinical validation) and IEC 80601-2-30 (automated non-invasive sphygmomanometers) - apply to the characteristics below and are set out more fully in Sections 5 and the Questionnaire (Annex IV).*

| Parameter | Minimal | Optimal |
|---|---|---|
| **Product category** | Non-invasive, intermittent, automated, or semi-automated electronic sphygmomanometer with upper arm cuff | As minimal, fully automated |
| **Intended use** | Measurement of blood pressure and pulse rate in pregnant and postpartum women at or near the home, by a CHW or by the woman herself with CHW support, as an adjunct to facility-based ANC measurement. Supportive monitoring; not for standalone diagnosis. | As minimal, with a labelled intended use claim explicitly covering lay/self-measurement and community (non-professional) use |
| **Target population** | Pregnant and postpartum women, including normotensive women, women with gestational hypertension and women with pre-eclampsia | As minimal |
| **Target user** | CHW or trained lay user (note: CHW status varies by country) | Pregnant woman herself, or a family member, after brief training-i.e. usable with minimal/no formal training |
| **Target setting** | Household / community (CHW home visit); also usable at Level 1 primary health facilities | As minimal |
| **Clinical validation (general population)** | The exact model offered has successfully met the acceptance criteria of ISO 81060-2:2018 for general-population clinical validation (minimum 85 participants), with the | As minimal, plus independent listing (e.g. STRIDE BP / VDL) |

| | | |
|---|---|---|
| | validation report or equivalent published evidence available for review | |
| **Validation in pregnancy (not an eligibility requirement)** | Not required to apply. Where the model has not been successfully validated in pregnant women per the pregnancy special-population requirements of ISO 81060-2:2018, SUPREME-SECURE may fund and conduct this for selected devices. Bidders state their status and willingness to support such a study and adopt the resulting labelling. | Successfully validated in pregnant women (including pre-eclampsia) in accordance with the pregnancy special-population requirements of ISO 81060-2:2018, published or independently listed for the exact model offered |
| **Cuff sizing** | Cuff(s) accommodating the range of arm circumferences found in the target antenatal population, including larger arms (indicatively from ~22 cm) | Cuffing that reliably fits the full range in the population, including a large-adult option (indicatively up to ~52 cm); cuffs individually orderable as spare parts |
| **Readout** | Clear numeric display of systolic / diastolic (mmHg) and pulse, legible by a lay user in bright daylight | As minimal, plus an interpretation aid that helps a lay worker recognise a reading requiring action - for example, a visual classification or alert against clinically defined thresholds for blood pressure. Additional features that support safe use in this setting, such as irregular-heartbeat detection, trend indication and availability of mean arterial pressure (MAP), are advantageous. The specific format of the interpretation aid is not prescribed. |
| **Memory** | Stores multiple timestamped readings on the device; readings retained when powered off or batteries are changed | Can support multiple user profiles, or a clear method of associating stored readings with the correct individual, option to export or transfer records to a health worker or record system |
| **Power** | Runs on a power source that is reliable and replaceable in low-resource settings, without dependence on mains electricity or proprietary components; battery-status indication; sufficient operating life between changes/charges for routine field use | Extended operating life and flexible charging suited to settings with limited mains power (e.g. batteries rechargeable with solar/via USB), while retaining a widely available power source; graded battery-status indication |
| **Environmental / durability** | Withstands routine transport, handling and the ambient temperature, humidity and dust of community use, and the number of measurement cycles expected over its service life (indicative targets: operating ~10–40 °C, ≤85% RH; survives a ~1 m drop) | Robust across a wider range of field conditions, with dust and splash resistance and tolerance of rougher handling (indicative targets: operating ~−20 to 55 °C, ≤90% RH; survives a ~2 m drop) |
| **Portability** | ≤ 500 g including cuff; carried in a CHW kit bag | ≤ 300 g including cuff; protective carry case included |
| **Calibration / servicing** | Maintains measurement accuracy over a defined service interval without per-user calibration; a calibration-check procedure that can be performed in-country is documented | No user calibration required over the service life; a simple means of verifying calibration is available, supported by an accessible calibration and repair route for the target countries |
| **Cleaning and disinfection** | Device and cuff can be cleaned and surface-disinfected between users using locally available agents, without damage; a documented cleaning procedure is provided (important for the shared-device CHW model). | Materials and design tolerate repeated disinfection over the service life; wipeable/low-porosity surfaces; guidance aligned with infection-prevention practice in the target settings. |
| **Connectivity** | None required (standalone operation with on-device display) | Optional data transfer to a health worker application or record system, structured in line with the WHO Digital Adaptation Kit for SMBP in pregnancy where applicable; the device remains fully functional without a phone or connection |
| **Labelling and training** | Pictorial instructions for use suitable for low-literacy users | Localised instructions and job aids in relevant national languages (for target countries); |

| | | |
|---|---|---|
| | | training package and demonstration materials for CHWs |
| Warranty and service | 2-year warranty; in-region service arrangement | 5-year warranty; in-country service, spare parts, and calibration |
| Consumables and replacement parts | Replacement cuffs, batteries, and other consumables/parts are identified and can be ordered separately; reliable in-country or regional availability to sustain functioning over the service life. | Guaranteed availability of cuffs, batteries, and spares for a defined period; multiple cuff sizes and common parts held or locally sourced; supply plan addressing the missing-cuff and battery-failure risks seen in the market assessment. |
| Regulatory status | CE marking, US FDA clearance, or approval by another SRA or the regulatory authority of an IMDRF founding member, for home use, for the exact model offered | As minimal, plus existing registration in one or more SUPREME-SECURE implementation countries |

*There is currently no WHO Prequalification pathway or other streamlined global pathway for blood pressure measuring devices. Requirements above are provisional and may be adjusted; the questionnaire (Annex IV) is the detailed reference.*

### 3.4 Market Overview

A market assessment conducted across the 5 project countries in 2026 found that health workers most often cite BP device reliability and functionality - rather than basic availability - as the main barrier to BP measurement: broken devices, battery failure, missing or single-size cuffs, absent calibration and no clear maintenance pathway were reported consistently. Devices in routine use are frequently not validated for use in pregnancy, and pregnancy validation is rarely verified at procurement.[4]

A technology landscape analysis conducted in May 2026 mapped digital BP devices across categories. Validated automated upper arm cuff devices are the most widely available category, distributed across sub-Saharan Africa at roughly USD 25–150, with select models validated for use in pregnancy. Among pregnancy-validated semi-automated devices, low-cost rugged models with built-in early-warning displays have been validated to ISO 81060-2 and British Hypertension Society standards in pregnancy and pre-eclampsia at approximately USD 25. Cuffless devices - smartphone applications (~USD 2/week) and wearables (~USD 299–399)-are an area of innovation but are not currently recommended for clinical use.[5]

The following cross-cutting gaps define the landscape. First, pregnancy-validated devices registered in project countries are registered for professional use rather than for community or self-care use. Second, evidence on home-based monitoring in LMICs is limited. The aim of supporting this product category is closing the evidence and scalability gaps that limit uptake of quality, fit-for-purpose technologies for this priority use case. This landscape was compiled from publicly available information; this RFP may identify additional technologies, including those in development.

Community focus group discussions and stakeholder interviews in Ghana, Kenya, Malawi, Senegal and Tanzania indicated appetite for improved access to BP monitoring between ANC visits, but limited support for unsupported self-monitoring: women, health workers and policymakers alike raised concerns about measurement accuracy and interpretation without a health worker present, and scepticism about app-based measurement. The clear preference was for community-based approaches that improve access and empower women through supported models-the basis for the scope in Section 3.1.[6]

*Sources: [1] ACOG Practice Bulletin 222 (2020); [2] von Dadelszen & Magee, Maternal-Fetal Medicine (2021); [3] WHO ANC coverage data / country HMIS; [4] SECURE BP market assessment (2026); [5] SECURE digital BP tools landscape analysis (2026); [6] SECURE community FGD reports (Ghana, Kenya, Tanzania, 2026).*

## Section 4: Scope of the RFP

### 4.1 Successful Bidder Commitments

As part of the partnership, the Successful Bidder(s) commit to the following activities, in an accelerated manner and in accordance with the timelines agreed during the programme support contracting process.

Applicable activities may vary by product maturity; bidders should indicate which activities are applicable to their product in the RFP questionnaire.

*The commitments below are primarily contributions of the manufacturer's product, documentation, technical input, and staff time. The evidence-generation study - covering both clinical validation and the operational assessment - is funded and conducted by SUPREME-SECURE (Section 4.2), not by the manufacturer. SUPREME-SECURE may also provide technical assistance and, where justified, financial incentives toward regulatory filing costs. The manufacturer's direct financial obligations are limited to those expressly stated (e.g. supplying study devices free of charge, and the cost of its own regulatory submissions where not otherwise supported); no other financial burden is implied by the commitments in this section.*

**Product readiness**

- Provide formal documentation confirming that the device design, components, firmware/software, cuff specification, labelling and manufacturing process have been finalised ("design lock").
- Where the device is not yet validated for use in pregnancy, agree to the scope and design of the required ISO 81060-2:2018 special-population study with SUPREME-SECURE and commit to the resulting labelling changes.
- Where the current intended-use claim covers professional use only, prepare and submit the documentation required to extend the intended use to lay/community use, including human factors / usability engineering evidence (IEC 62366-1) and instructions for use adapted for low-literacy users.

**Evidence generation**

- Supply devices, cuffs, spare parts, consumables, and technical documentation to SUPREME-SECURE, free of charge, in the quantities and within the time limits required for the clinical and operational evaluations planned under SECURE. *This free-of-charge supply is limited to the quantities needed for the SECURE evaluations only; it is not an open-ended or commercial-scale supply obligation.*
- Participate in and support an evidence-generation study in Ghana and Kenya, conducted in accordance with applicable regulatory requirements and internationally recognised standards. The study may encompass both (i) clinical validation of the device in pregnant and pre-eclamptic populations against a pregnancy-validated reference device or other recognised reference standard, and (ii) an operational assessment of the CHW-supported home-based measurement model - covering feasibility, acceptability, usability, equity (including gender-sensitivity), operational outcomes and costs from health-system and patient perspectives. *This study is funded and conducted by SUPREME-SECURE (see Section 4.2). The Successful Bidder is not expected to fund or run the study; the manufacturer's contribution is the supply of devices/materials, technical input, and staff time.*
- Provide technical support and expert input to SUPREME-SECURE study teams throughout the evidence generation process, including rapid response to protocol questions, device troubleshooting, replacement units, and review of preliminary data. *This refers to the manufacturer's own technical/staff input to the SECURE-run study; it does not require the manufacturer to fund the study itself.*
- Agree to the publication and dissemination of study results, including where results are unfavourable, in accordance with the data-sharing terms of the programme support contract.

**Quality management standards**

- If selected for award, permit and successfully complete a quality-system assessment of applicable manufacturing sites to verify compliance with ISO 13485:2016. Where valid ISO 13485 certification and SRA documentation are held, this may be conducted as a desk review; an on-site assessment (by SUPREME-SECURE and/or an independent third party) will be used only where required.
- Maintain compliance with all applicable product safety, performance, electromagnetic compatibility, and risk-management standards throughout the term of the Agreement (including, as applicable, the IEC 60601 series, IEC 80601-2-30, ISO 81060-1/-2, ISO 14971, and IEC 62366-1). Objective evidence of conformity is requested in the questionnaire (Annex IV).

**Regulatory approvals (upon successful evaluation)**

- For products not already approved for home use by an SRA or the regulatory authority of an IMDRF [1]founding member for home use, selected manufacturers would be expected to prepare and submit a regulatory dossier to at least one such authority in accordance with timelines agreed during contracting. *SUPREME-SECURE may provide technical assistance for dossier preparation, and financial incentives to offset regulatory filing preparation and submission fees may be available (see Section 4.2). This is not solely a manufacturer-funded activity.*
- Undertake product registration in at least 2 SUPREME-SECURE implementation countries, including Ghana and Kenya (final list to be agreed during workplan discussions), under an intended use covering community/lay use where the national regulatory framework permits. *Registration support, including technical assistance and possible financial incentives toward filing fees, may be provided by SUPREME-SECURE (see Section 4.2).*
- Maintain valid product registrations in target countries for the duration of the programme support agreement.
- Commit to pursue WHO Prequalification *if and when* WHO establishes a pathway covering blood pressure measuring devices for self- or community/lay use.

**Commercialisation and supply**

- Supply the product to eligible procurement entities at or below an agreed transparent and affordable access price, for a period and under terms to be specified in the programme support contract. Access pricing is intended to cover such elements as the device, cuffs and spare parts, installation/commissioning where applicable, training, service, calibration, and required maintenance - the precise scope to be agreed during contract negotiation.
- Prepare a production and supply plan demonstrating capacity to supply qualified orders with a standard manufacturing lead time (to be specified in the contract) and scale-up capacity in line with projected demand in SUPREME-SECURE implementation countries.
- Commercialise the product in target implementation countries following registration - including distribution, training, service, calibration and after-sales support, and guaranteed availability of replacement cuffs and spare parts for a minimum period to be agreed.
- Engage with global and regional procurement platforms to list the product and enable broad procurement access at or below the agreed access price, following regulatory authorisation.

**Collaboration and reporting**

- Establish a joint project team structure with the Aurum Institute and CHAI and participate in regular project meetings (in person and/or via videoconference) as required under the programme support contract.
- Submit regular progress reports covering design-lock and development milestones and study readiness; validation and operational study progress; regulatory plans, submissions, and approval status; country registration activities; and commercialisation and supply activities.
- Provide transparency on funding received or pending from other donors or stakeholders for activities that overlap with or relate to the scope of work in this Section 4.
- Acknowledge Unitaid's funding support in public communications related to activities conducted under this programme, as required under the programme support contract.

## 4.2 Types of Support Available

As part of the partnership, SUPREME-SECURE will provide the following types of support to Successful Bidder(s):

- Fund and conduct an evidence-generation study in Ghana and Kenya, encompassing both (i) clinical validation of device performance in pregnant and pre-eclamptic populations, benchmarked against a pregnancy-validated reference device, to support regulatory submissions and inform device selection; and (ii) an operational assessment of CHW/woman-performed measurement - accuracy, acceptability,

[1] The regulatory authorities of the Founding Members of IMDRF includes USA, European Commission, Japan, Canada and Australia.

feasibility, usability, cost, equity (including gender-sensitivity) and health-system effects. (Analytical calibration checks against reference equipment are a manufacturer responsibility; only devices with these in place will be selected.)

- Prepare and share a performance evaluation report.

SUPREME-SECURE may also provide the following, pending successful validation, to support regulatory and market entry readiness:

- **Technical Assistance:** subject-matter expertise (directly or via consultants) in technical documentation, validation and study protocol development, human factors, and usability engineering, labelling and intended-use extension, regulatory strategy, dossier preparation and submission, and quality management systems. Commercial advisory and LMIC launch support can be included subject to successful clinical validation.
- **Financial Incentives:** financial subawards to offset regulatory filing preparation and submission fees can be considered, if justified by the Bidder and approved by the Independent Review Panel (IRP) and Unitaid. Availability and quantum are subject to the product support justification process.

All support to be provided under SUPREME-SECURE is subject to approval from Unitaid and the IRP.

### 4.3 Conditions of Programme Support

Programme support will be subject to the following conditions, to be formalised in a programme support contract between the Aurum Institute (and CHAI) and the Successful Bidder:

- Development, validation, and commercialisation timelines agreed during contracting, including key milestone dates.
- Agreed access price for eligible procurement entities for the duration of the grant period and beyond, with associated terms and supply conditions.
- Country registration commitments in SUPREME-SECURE implementation countries, in accordance with agreed timelines.
- Transparency on progress, including regular reporting and openness to quality audits and a financial forensics audit.
- Acknowledgement of Unitaid's funding support in relevant public communications.
- Termination clause: failure to achieve a minimum set of agreed milestones may result in termination of the programme support contract and forfeiture of any remaining incentive payments.

Programme support contracts are subject to Unitaid's review and approval prior to execution.

## Section 5: Eligibility Criteria

This RFP is open to bidders that meet all the following minimum eligibility criteria. Proposals from bidders that do not satisfy all eligibility criteria will not be considered for further evaluation.

#### Who may apply (bidder categories)

This RFP is open to **device manufacturers only.** In line with Unitaid guidance and CHAI internal alignment, only the Legal Manufacturer of an eligible device may respond to this RFP. Distributors, agents, resellers and other third parties that are not the Legal Manufacturer are not eligible to apply.

The **Legal Manufacturer** is the natural or legal person ultimately responsible for the design, manufacturing, packaging, labelling, intended use, quality, safety, performance, regulatory compliance and lifecycle management of the product, and for maintaining the technical documentation, quality management system, regulatory approvals and post-market surveillance/vigilance. This includes the ability to make labelling and intended-use changes to the product, which is required to deliver the objectives of this RFP.

A proposal submitted by any party other than the Legal Manufacturer will be deemed non-responsive.

#### Product and technology eligibility

- The product is an automated or semi-automated upper arm cuff blood pressure measuring device as described in Section 3.2. Cuffless devices (including smartphone applications and cuffless wearables),

wrist- and finger-cuff devices, and manual auscultatory devices are not eligible under this RFP, for the reasons set out in Section 3.2.

- The Bidder produces or is developing a product meeting the key specifications in Section 3.3, with documented design lock.
- The exact model offered has successfully met the acceptance criteria of ISO 81060-2:2018 for general-population clinical validation (minimum 85 participants), with the validation report or equivalent published evidence available for review.
- Validation in a pregnant population is not required to apply. Bidders should disclose whether the exact model offered has been successfully validated in pregnant women (including gestational hypertension and pre-eclampsia) per the pregnancy special-population requirements of ISO 81060-2:2018 and confirm willingness to support such validation and adopt the resulting labelling if not already validated in this population. (Support that SUPREME-SECURE may provide toward such validation is described in Section 4.2.

**Regulatory capability and readiness**

The Bidder must demonstrate the regulatory capability and organisational capacity to support product registration and lifecycle management in the target countries. As a minimum, the Bidder shall provide:

- Evidence of previous regulatory submissions and approvals for the proposed device or a comparable medical device.
- Details of existing product registrations, particularly within Africa and other LMICs.
- Current regulatory status of the proposed device.
- A summary of regulatory documentation available to support submissions (technical documentation, clinical evidence, and quality-management certification); and
- An outline of the proposed regulatory strategy and timelines for registration in the SUPREME-SECURE implementation countries, including Ghana and Kenya.
- Confirmation that the Bidder has obtained, is actively pursuing, or commits to obtaining-with a credible, time-bound plan-approval for the submitted version of the device from a Stringent Regulatory Authority (SRA) or the regulatory authority of an IMDRF founding member.
- Willingness to pursue an intended-use claim, and corresponding labelling, covering lay/community use of the device in pregnancy where the applicable regulatory framework permits.
- Confirmation that the Bidder will maintain regulatory compliance throughout the contract term and promptly notify SUPREME-SECURE of any change affecting the regulatory status, intended use, certification, labelling, manufacturing site, QMS certification or market authorisations of the device.

**Quality and manufacturing standards**

- All applicable manufacturing sites operate under a QMS certified to ISO 13485:2016, or have a documented, credible, and time-bound plan to achieve certification. Valid ISO 13485 certificates shall be provided upon request.
- The proposed device conforms to all applicable product safety, performance, EMC, and risk-management standards. Where conformity has not yet been demonstrated, the Bidder provides a documented, credible, and time-bound plan for achieving it prior to supply. Objective evidence of conformity (accredited test reports, Declarations of Conformity or other recognised evidence) shall be provided upon request.

**Financial eligibility**

- The Bidder demonstrates adequate financial solvency and operational stability to fulfil the commitments in Section 4.1. This is usually verified by three years of financial statements; a financial audit may be requested at the discretion of SUPREME-SECURE.

**Supply capacity**

- The Bidder can supply devices, cuffs, and spare parts in sufficient quantities and within a time limit in line with the planned performance evaluation and operational studies, to be agreed during contracting.

- Pending successful validation, the Bidder has sufficient production capacity to supply qualified procurement orders at scale, or a credible plan to develop it.

**Supporting documentation**

The Bidder shall provide supporting documentation sufficient to substantiate the regulatory, quality and technical claims in its proposal (e.g. evidence identifying the Legal Manufacturer; valid ISO 13485 certification; Declarations of Conformity; evidence of existing approvals/registrations; conformity test reports; a technical-documentation index; current labelling/IFU and intended-use statement; and any pending submissions). Detailed requirements are set out in the questionnaire (Annex IV). Where any required evidence is not yet available, the Bidder shall clearly identify this and provide a time-bound plan.

# Section 6: Instructions to Bidders

## 6.1 What to Submit

Bidders are required to submit a complete proposal package consisting of:

1. Annex I – Declaration (Form A): completed, signed, and dated.
2. Annex II – Quality Audit Agreement (Form B): completed and signed, confirming willingness to permit SUPREME-SECURE and/or an appointed third party to conduct quality-system assessments of applicable manufacturing sites if selected.
3. Annex III – Financial Forensics Audit Agreement (Form C): completed and signed, confirming willingness to participate in a financial forensics audit if requested.
4. Annex IV – RFP Excel Questionnaire: fully completed. Supporting documents as separate attachments, not embedded in the Excel.

All proposals must be in English and signed by a duly authorised representative. Proposals received after the deadline will not be considered. No fee is required. Bidders must also disclose any funding received from or pending with other donors for activities overlapping with Section 4.

## 6.2 How to Submit

By email to secure.rfp@auruminstitute.org. Subject line: RFP-PE005-SECURE – [Bidder Organization Name]. Files as PDF or Excel; supporting documents as separate attachments.

## 6.3 Enquiries and Q&A Process

An FAQ document is available from the RFP webpage. Questions not covered by the FAQ can be directed to the Aurum Institute by email (secure.rfp@auruminstitute.org). Unitaid and other consortium members will not respond to enquiries. All questions must be submitted via email; telephone enquiries will not be accepted. An informational session will be held (Section 7); bidders can register via [link]. Questions submitted to date are answered during the session and compiled into the FAQ, which is updated throughout the submission period and is the sole mechanism for responding to queries after the session.

## 6.4 Changes in Circumstances

Bidders must promptly notify the Aurum Institute in writing of any change in circumstances that may affect their eligibility or capacity to perform.

## 6.5 Costs of Preparing a Proposal

All costs of preparing and submitting a proposal are the sole responsibility of the Bidder. The Aurum Institute, CHAI and Unitaid will not reimburse any such costs.

## 6.6 Bid Validity

Proposals remain valid for a minimum of 120 days from the submission deadline; shorter validity will be deemed non-responsive.

# Section 7: Process and Timeline

## 7.1 Overview

The SUPREME-SECURE supplier selection process is subject to independent oversight by the Independent Review Panel (IRP). The following dates are indicative and subject to change; bidders will be notified of any changes.

| Activity | Deadline |
|---|---|
| RFP posted publicly and released to potential Bidders | 18 August 2026 |
| Informational session for potential Bidders | 25 August 2026 |
| Deadline for Bidder questions (email only) | 1 September 2026, 23:59 CAT |
| Consolidated Q&A published | 8 September 2026 |
| Proposal submission deadline | 15 September 2026, 23:59 CAT |
| Shortlisted manufacturers notified | 7 October 2026 |
| One-to-one manufacturer meetings | 12-23 October 2026 |
| Shortlisted manufacturers submit revised RFP responses | 4 November 2026, 23:59 CAT |

## 7.2 Informational Session

An informational session will be held on **25 August 2026** via Zoom. Register via the following **Registration Link**

Questions submitted via the link or the RFP email address will be answered during the session. Joining details will be posted on the Aurum Institute website and relevant consortium partner websites. After the session, all further enquiries must be submitted in writing via Section 6.3.

# Section 8: Evaluation Process and Criteria

## 8.1 Overview

The Aurum Institute and CHAI will form an evaluation committee. Proposals are first screened against the Section 5 eligibility criteria; eligible proposals are then assessed against the technical and financial criteria below. Shortlisted bidders will be invited to one-to-one meetings and may be asked to submit revised responses. The process is subject to IRP oversight, and final selection is presented to and aligned with Unitaid (Scoring is applied here only; eligibility is a separate pass/fail screen in Section 5.)

## 8.2 Evaluation Criteria

To be successful, the Bidder must demonstrate the technical, regulatory, manufacturing, and commercial capability to supply the proposed device at scale while supporting product registration and lifecycle management in the implementation countries. The Evaluation Committee will assess both the information provided and the supporting evidence submitted. Greater weight will be given to demonstrated compliance supported by objective evidence (e.g. regulatory approvals, certificates, accredited test reports, technical documentation) than to statements of future intent; where a Bidder proposes to obtain a certification, approval or claim after award, the credibility, feasibility and timing of the plan will be evaluated.

| Criterion | What will be assessed |
|---|---|
| **Device performance and validation status** | Accuracy and validation evidence against ISO 81060-2:2018, including any pregnancy/pre-eclampsia special-population validation for the exact model; independent listings; measurement range and repeatability. |

| Criterion | What will be assessed |
|---|---|
| **Fit to the home-based / CHW-supported use case** | Usability for lay and CHW users, interpretation aids, cuff sizing, readability, portability, durability, power resilience, and suitability for shared use across a caseload. |
| **Manufacturing capability and capacity** | QMS maturity; ISO 13485 status; conformity with applicable IEC/ISO standards; manufacturing capability and scalability; production capacity; lead times; supply-chain resilience; availability of cuffs, accessories, and spare parts; willingness to participate in quality assessments. |
| **Regulatory strategy** | Existing approvals and registrations; regulatory strategy for implementation countries; completeness of supporting documentation; credibility of plans to obtain SRA or IMDRF founding-member approval; preparedness for WHO PQ should it become applicable; lifecycle-management capability; approach to obtaining lay/community-use claims. |
| **Prior experience and quality track record** | LMIC deployment experience, field performance, post-market surveillance and complaint history, service, and calibration networks. |
| **Implementation plan and timelines** | Credibility and feasibility of the proposed plan -regulatory milestones, manufacturing readiness, production scale-up, country registrations, supply timelines, and alignment with SUPREME-SECURE milestones. |
| **Financial criteria** | Access price, with associated terms and supply conditions; volume-based pricing schedules and value for money; total cost of ownership over the device service life. |

In addition, the evaluation team will consider environmental and climate-smart manufacturing practices (energy efficiency, sustainable packaging, repairability, battery and e-waste management, regional production) and gender-related organisational policies (e.g. female leadership and workforce representation) as secondary considerations, factored in where proposals are otherwise comparable.

## Section 9: Reservation of Rights and Legal Disclaimer

This RFP must not be construed as a recommendation, offer or invitation to enter into a contract, agreement, or any other arrangement. It is an invitation for the submission of proposals only and does not legally oblige the Aurum Institute to accept any proposal in whole or in part. The issuance of this RFP does not create any contractual obligation or binding legal relationship between any Bidder and the Aurum Institute until and unless the Aurum Institute issues a formal Letter of Acceptance and a programme support contract is signed by duly authorised representatives of both parties.

The Aurum Institute, CHAI and Unitaid make no representation or warranty, and shall incur no liability, as to the accuracy, reliability, or completeness of the information in this RFP.

The Aurum Institute, CHAI and Unitaid will not reimburse or bear any costs associated with preparing and submitting a proposal. No fee is required.

Information submitted that the Bidder considers commercially confidential or proprietary should be clearly marked as such. The Aurum Institute, CHAI and Unitaid will take all reasonable measures to protect such information and will not share it outside the evaluation process without the Bidder's prior written authorisation, except where such information: (a) was already known prior to disclosure; (b) was in the public domain at disclosure; (c) subsequently enters the public domain through no fault of the aforementioned parties; or (d) becomes available from a third party not in breach of any confidentiality obligation. Information not marked confidential or proprietary will not be shared in a manner identifying individual manufacturers without authorisation but may be used in anonymised or aggregated form.

All enquiries must be directed to the contact in Section 6.3. Neither Unitaid nor any other consortium member will respond to RFP-related enquiries.

The evaluation committee reserves the right to:

- Accept or reject any or all proposals, in whole or in part, without assigning reasons and without incurring liability.
- Annul the RFP process, in whole or in part, at any time without prior notice.
- Add, modify, alter, or revoke the RFP and its terms, with notification to registered/submitted Bidders.
- Extend any deadline.
- Request additional information, arrange interviews or presentations, visit facilities, or conduct audits to verify information.
- Shortlist more or fewer Bidders than indicated if warranted by the quality of proposals.
- Award programme support to more than one manufacturer where consistent with project goals and the approved product support justification.

## Annex I: Declaration (Form A)

This form must be completed, signed, and returned to **the Aurum Institute**

**DECLARATION**

I, the undersigned, being duly authorised by _____ (company name), having read the RFP for automated and semi-automated upper-arm cuff blood pressure measuring devices for home-based monitoring in pregnancy, submit our proposal, which includes the information requested in Section 6. I confirm that all the information provided is correct.

I confirm that we are interested in entering discussions for a possible collaboration with the Aurum Institute and CHAI on the verification and validation, manufacture, filing to SRA bodies, WLA bodies, founding members of IMDRF, and national regulatory authorities in SUPREME-SECURE implementation countries, and commercialization of blood pressure measuring devices for home-based monitoring in pregnancy according to the terms of this RFP.

I understand that the issue of the RFP and the proposal we submit is not a commitment by either party to enter into such discussions or collaboration. I further understand that the Aurum Institute reserves the right to discuss and collaborate with one or multiple parties, no parties, or to cancel this RFP at its sole discretion.

This RFP and any proposals thereto shall be the property of the Aurum Institute and CHAI.

I, who am duly authorized to act on behalf of the above-named organization, hereby certify that:

- The information provided in this proposal, including all annexures and supporting documents, is accurate, complete, and not misleading.
- The organization I represent is eligible to participate in this RFP and meets all eligibility criteria set out in Section 5.
- The organization I represent agrees to comply with the WHO Code of Ethics; the WHO Policy on Preventing and Addressing Sexual Misconduct; the WHO Policy on Preventing and Addressing Abusive Conduct; the WHO Code of Conduct for Responsible Research; the WHO Policy on Preventing and Addressing Retaliation; the WHO Policy on Prevention, Detection and Response to Fraud and Corruption; and the UN Supplier Code of Conduct, in each case as amended from time to time, and which are publicly available on the WHO website at the following links: http://www.who.int/about/finances-accountability/procurement/en/ for the UN Supplier Code of Conduct and http://www.who.int/about/ethics/en/ for the other WHO Policies.
- No official, employee, or officer of the Aurum Institute, CHAI, Unitaid, or any consortium partner has received or has been offered any individual benefit in connection with the preparation or submission of this proposal.

| | |
|---|---|
| **Name of authorized representative:** | |
| **Title:** | |
| **Signature:** | |
| **Date:** | |
| **Company name:** | |
| **Postal address:** | |
| **Telephone number:** | |
| **Email address:** | |

## Annex II: Quality Audit Agreement (Form B)

This form must be completed, signed, and returned to the Aurum Institute

### QUALITY AUDIT AGREEMENT

The organization named below (the "Bidder") hereby agrees that, in the event it is selected as a Successful Bidder under this RFP, it will provide permission for the Aurum Institute and/or its designated representative, at its cost, to conduct a quality assurance audit of all applicable manufacturing sites, in order to verify compliance with ISO 13485 and applicable SRA standards.

Such audits may be conducted by an independent third-party consultant appointed by the Aurum Institute. Audits will be scheduled directly with the Bidder prior to or following the award of program support. The Bidder agrees to provide reasonable access to relevant personnel, documentation, and facilities during the audit.

This agreement does not constitute a commitment to award program support to the Bidder.

| | |
|---|---|
| **Organization / Company** | |
| **Name of authorized representative** | |
| **Title** | |
| **Signature** | |
| **Date** | |

## Annex III: Financial Forensics Audit Agreement (Form C)

This form must be completed, signed, and returned to the Aurum Institute

**FINANCIAL FORENSICS AUDIT AGREEMENT**

The organization named below (the "Bidder") hereby agrees that, in the event it is selected as a Successful Bidder under this RFP, it will provide permission for the Aurum Institute and/or its designated representative, at its cost, to conduct a financial forensics audit of the Bidder's relevant financial records and accounts, in order to assess the Bidder's financial capacity to perform the activities outlined in this RFP. This right will be exercised at the discretion of SUPREME-SECURE given an initial assessment of the financial risk and size and nature of financial support to be provided.

Such audits may be conducted by an independent third-party consultant. Audits will be scheduled directly with the Bidder following the award of program support. The Bidder agrees to provide reasonable access to relevant personnel, documentation, and facilities during the audit.

This agreement does not constitute a commitment to award program support to the Bidder.

| | |
|---|---|
| **Organization / Company** | |
| **Name of authorized representative** | |
| **Title** | |
| **Signature** | |
| **Date** | |

## Annex IV: RFP Questionnaire

The RFP Excel Questionnaire is provided as a separate attachment to this document and must be completed and submitted as part of the proposal package. The Questionnaire is structured as follows:

| Tab | Section Title | Content |
|---|---|---|
| A | **Instructions** | How to complete and submit the questionnaire. |
| B | **General** | Legal name, registered address, key contact details, company overview, and authorized signatory. |
| C | **Device information** | Model(s) offered, design-lock status, measurement technology, cuff range and sizes, display and interpretation aids, memory, power, connectivity, durability and environmental specifications, weight and dimensions, service life. |
| D | **Performance and validation** | ISO 81060-2:2018 general and special-population (pregnancy, gestational hypertension, pre-eclampsia) validation status and reports; independent listings; bench/type-test reports; conformity to IEC 60601 series and IEC 80601-2-30. |
| E | **Usability and human factors** | Human factors / usability engineering file (IEC 62366-1), instructions for use, low-literacy adaptations, languages available, training materials, evidence of lay-user performance. |
| F | **Manufacturing information** | Manufacturing sites, capacity, lead times, QMS status and ISO 13485 certification, post-market surveillance, and complaint history. |
| G | **Development plan and timelines** | Proposed activities, milestones and Gantt chart for any remaining validation, regulatory filing, registration, and commercialization. |
| H | **Regulatory** | Current regulatory approvals (SRA/WLA/IMDRF, national), current intended-use claims, planned submissions and timelines, plan for lay/community intended-use claim, target country registration plan. |
| I | **Pricing** | Ex-works pricing (USD) for device, cuffs, and spare parts across volume tiers; minimum order quantity; warranty; service, calibration and maintenance offer and pricing; total cost of ownership; other supply conditions. |
| J | **Gender & Climate** | Organizational policies and practices relating to gender equity in the workplace and environmental sustainability, including packaging, repairability, battery and e-waste management. |

Supporting documents (e.g. validation reports, ISO 13485 certificates, IFU, audit reports) should be submitted as separate file attachments. Please do not embed documents within the Excel file.

Bidders should not alter the structure of the tabs or the questions. Where a question is not applicable, please indicate N/A and provide a brief explanation.