

Appendix 1 - Buyer's requirement specification

Table of contents

1 Purpose of the procurement	1
2 Confidentiality	1
3 The scope and content of the procurement	2
3.1 General description	2
3.2 Details at sub-system level.....	2
3.3 Compliance needs	10
3.4 Deliverables	11
4 Requirements for documentation, information etc.	12
5 Training	13
6 Table of requirements	13

1 Purpose of the procurement

The purpose is to develop production design of an instrument with optical, optomechanical, computational, thermal, electronic and power components with a constraint of design being MDR Class 2A compliance ready; and having the design tested on ground through at least two production prototypes. Details in this document refer to two prototypes, but the same details will by default apply to all prototypes covered under the contract.

This procurement is expected to lead to a production ready design of the instrument compatible for manufacturing in batches of 10-50 units at a time initially at a site not necessarily the same as the suppliers' site. We also expect to receive a fair estimate of the production costs of the instrument when it is launched commercially. The supplier is also expected to provide necessary technical documentation which we would need for CE application for a MDR Class 2A device.

2 Confidentiality

Procurement is tied to confidentiality, with many IPs involved. All suppliers need to have signed an NDA with UiT regarding IP handling before more details of the requirements of the solution can be disclosed.

The explicit details of the pertinent biological cells, software and platform specs, laboratory-level optical and optomechanical designs, sample management workflows, relevant specs of microfluidic cartridge, user interface, etc. will be shared after NDAs are signed. After signing the NDA additional documents relevant for providing a tender can be shared by request.

The contract terms will mandate that all the information being shared by UiT after signing the NDA is considered IP sensitive and confidential by default, that all the background IP of UiT shared in the context of this contract is used only for this contract and no other contract, that all the work and intellectual property generated by the supplier as a part of this contract will belong to UiT. Any non-IP sensitive or procedural knowledge generated by the supplier may be used by the supplier elsewhere. The supplier also retains the right to their own background IP generated before this project or independent of it. These terms need to be explicitly included in the contract, although the supplier is permitted to propose minor negotiations within the general scope of the above terms.

3 The scope and content of the procurement

3.1 General description

The instrument shall be developed as an integrated medical-device hardware platform supporting our custom microfluidic-based biological cell-processing and motility-imaging workflow. The platform shall provide cartridge positioning, optical imaging, illumination, X/Y/Z positioning, localized thermal regulation, control electronics, firmware, power architecture, enclosure, harnessing and service access. Tenders shall also include compliance-test-ready documentation.

The instrument shall accept a customized microfluidic cartridge, locate it repeatably relative to the optical axis and cartridge thermal-control region, and accommodate UiT-defined sample-flow and electrode-contact interfaces. The optical subsystem shall image the defined cartridge/sample region, with controlled illumination and motion/focus capability sufficient to support UiT software access to usable image streams.

The instrument shall regulate the cartridge/sample thermal-control region to a nominal 37 °C target, using localized sensing, heating/cooling hardware, firmware control, and defined thermal fault behavior. Compute, illumination, power, and enclosure heat shall be managed to avoid material disturbance of the cartridge-region thermal-control loop.

The compute architecture shall use an off-the-shelf Ubuntu-compatible platform for image-acquisition and analysis software. Deterministic low-level hardware control shall be implemented through a dedicated control PCB or electronics assembly and embedded firmware, including thermal control, illumination control, fan control, sensor acquisition, power-state monitoring, diagnostics, and fault handling.

3.2 Details at sub-system level

The device shall be organized as an integrated benchtop instrument, with the enclosure, internal frame, power architecture, electronics, optics, motion hardware, cartridge interface, and thermal subsystem

designed as a single serviceable platform rather than as a laboratory assembly of independent modules. Some more details are included below to help the suppliers assess the nature of work.

Custom microfluidic cartridge interface: The instrument shall provide a cartridge interface that locates the UiT-defined Customized microfluidic cartridge relative to the optical axis, thermal-control region, motion stack, and service access path, specified as:

- **Cartridge location guidance:** Primary/secondary/tertiary datum features, guided insertion path, controlled end-stop, repeatable seating plane, and misorientation resistance where practical.
- **Optical interface:** Clear imaging aperture aligned to microscope optical axis, illumination path, objective working distance, required field of view, and Z-axis focus range.
- **Thermal interface:** Local heat-transfer region near the sample zone, compatible with temperature-sensor placement, heater/TEC placement, contact pressure control, and cartridge deformation limits.
- **Fluidic and electrode accommodation:** Space claims, access windows, securing/clamp features, and mechanical clearance for UiT-defined sample-flow interfaces, electrode contacts, and cartridge peripherals used to support Customized microfluidic operation.
- **Routing and serviceability:** Defined cable/tubing paths away from optical aperture, moving stages, thermal elements, and cartridge-removal path; access for installation, removal, inspection, cleaning, and troubleshooting.

Optical imaging subsystem: The instrument shall include an integrated microscope imaging subsystem that provides repeatable image acquisition through the UiT-defined Customized microfluidic cartridge window, specified as:

- **Component selection:** Off the shelf camera, microscope objective, tube lens, illumination optics, diffuser/condenser elements, beamsplitter or equivalent optical routing, and rigid optomechanical mounting.
- **Optical path alignment:** Repeatable alignment of camera sensor plane, objective/lens stack, illumination path, cartridge imaging window, and sample region, with datum references compatible with the cartridge interface and motion stack.
- **Camera interface:** Ubuntu-compatible direct image-stream access by UiT software, bandwidth compatible with the selected resolution/frame-rate requirement, and mechanical/electrical integration suitable for service.
- **Focus and field of view:** Objective working distance, optical magnification, field of view, depth of field, and Z-axis focus range compatible with the UiT-defined imaging region and cartridge-window geometry.
- **Illumination compatibility:** Optical path compatible with stable transmitted-light or equivalent microscopy illumination, exposure control, diffuser/condenser placement, and thermal separation from the sample region.

- **Mechanical stability:** Rigid optical mounting structure with controlled backlash, limited vibration sensitivity, minimized cable-induced movement, and bounded alignment drift during normal handling and service.

Illumination sub-system: The instrument shall include a controlled illumination subsystem compatible with the selected microscope imaging configuration and the UiT-defined Customized microfluidic imaging region, specified as:

- **Illumination architecture:** Transmitted-light microscopy or equivalent configuration compatible with the UiT's current optical path, cartridge geometry, imaging window, objective selection, and camera exposure requirements.
- **Light source:** Off-the-shelf LED or equivalent stable illumination source with suitable wavelength range, output intensity, spatial uniformity, lifetime, availability, thermal load and integration compatibility.
- **Illumination control:** Hardware or firmware-controlled enable/disable, intensity adjustment.
- **Optical conditioning:** Diffuser, condenser, lens, aperture, or equivalent beam-conditioning elements to support usable field uniformity, contrast, and exposure stability across the required imaging region.
- **Thermal management:** Physical separation, heat sinking, airflow, duty-cycle control, or other mitigation to prevent illumination heat from materially disturbing the sample-region thermal-control loop.
- **Driver implementation:** Control-PCB-integrated driver (or off-the-shelf LED driver), selected based on the electric current requirement, noise behavior, thermal load, dimming method, firmware-control needs, availability, and pre-compliance risk.

Sample positioning and focus subsystem: The instrument shall include X/Y/Z positioning capability for sample-region location, image-field selection, and focus adjustment using the UiT-identified translation stage architecture or equivalent commercially available motion components, specified as:

- **Motion architecture:** Off the shelf X/Y/Z motorized stage system with controller interface, travel range, payload capacity, step resolution, repeatability, backlash, and mechanical stiffness compatible with the selected optical stack and cartridge interface.
 - **X/Y positioning:** Sample-region navigation across the Customized microfluidic imaging area, with movement range, incremental jog behavior, positional repeatability, and image-return behavior suitable for locating defined regions of interest.
 - **Z-axis focus:** Objective/sample-plane focus adjustment with travel range, fine-step control, backlash control, and mechanical stability compatible with the objective working distance, depth of field, cartridge seating tolerance, and focus-return requirement.

- **Controller interface:** Controller interface accessible from service software, UiT software, or defined hardware-control interface; homing, jog, position reporting, enable/disable, and fault/status behavior.
- **Safe-state behavior:** Motion disable, controlled stop, manual override or fault response during power-down, controller fault, user stop command, limit condition, or service-mode interruption, as supported by selected motion hardware.

Thermal regulation subsystem: The instrument shall include localized thermal regulation around the Customized microfluidic cartridge/sample region, with control applied to the cartridge thermal-control region rather than to the full instrument volume, specified as:

- **Thermal target:** Nominal $37\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ control target at the cartridge thermal-control region.
- **Temperature sensing:** Temperature sensor(s) positioned near the cartridge/sample region.
- **Heating/Cooling element:** TEC/Peltier element (or resistive heater) selected based on heating/cooling requirement, warm-up time, heat flux, control stability, mechanical integration, and thermal load from adjacent subsystems.
- **Thermal interface:** Contact surface (with heat spreader, if required), compliant pad, etc.
- **Control loop:** Closed-loop firmware control with warm-up/cool-down behavior, hold behavior, temperature stability monitoring, actuator limits, sensor-fault handling, and over-temperature response.
- **Heat rejection:** Heat sinking, fan-assisted airflow, enclosure ventilation, and thermal path control for dissipating heat from the TEC hot side, illumination source, electronics, and adjacent heat-generating subsystems.
- **Thermal isolation:** Compute/illumination heat separation to prevent adjacent subsystem heat from materially disturbing cartridge-region control.
- **Status and diagnostics:** Temperature reporting, TEC element state reporting, fault state reporting, and logged or viewable thermal data sufficient for engineering verification and service troubleshooting.

Compute platform and data path: The instrument shall include or accommodate an off-the-shelf Ubuntu-compatible compute platform capable of running UiT's benchmarking, image-acquisition, and image-analysis software while maintaining a clean data path to the imaging, motion, and control subsystems. Supplier will select this platform based on the specifications here:

- **Compute platform:** Off-the-shelf mini-PC, workstation, embedded GPU computer, or equivalent Ubuntu-compatible platform selected based on compatibility with UiT software, GPU compute headroom, VRAM requirement, RAM requirement, camera bandwidth, driver support, availability, serviceability, thermal load, safety certifications, and cost.

- **Camera data path:** Direct high-bandwidth connection between selected camera(s) and compute platform, with interface selection compatible with camera protocol, frame rate, resolution, bit depth, sustained acquisition duration, and UiT software access.
- **Control and motion interfaces:** Compute-platform communication with control PCB/electronics assembly, firmware diagnostics, illumination control, thermal-status reporting, and service-mode commands through USB or equivalent interface as appropriate.
- **Mechanical and thermal integration:** Compute mounting, ventilation, cable access, service access, fan/airflow path, and segregation of compute heat from cartridge/sample thermal-control region where practical.
- **Power integration:** Compute power architecture compatible with selected platform, supply strategy, startup/shutdown behavior, grounding approach, service access, and pre-compliance risk.

Note that suppliers are not expected to develop custom compute board or motherboard, unless the supplier shows proof of cost/performance advantage and fits it within the budget without compromising other specifications/needs.

Control electronics and PCB: The instrument shall include a custom control PCB (or control electronics assembly) for deterministic hardware control, subsystem monitoring, fault handling, and service diagnostics. The control electronics shall manage low-level instrument functions and shall not replace the compute platform.

A. Controlled circuits include:

- **Illumination driver:** Constant-current LED driver or PWM LED-driver interface; enable/disable, intensity control, current limiting, and diagnostic access where practical.
- **Thermal driver:** MOSFET, H-bridge, TEC/Peltier driver, resistive-heater driver, or equivalent output stage; current capacity, polarity control, PWM/control method, and fault-disable behavior matched to the selected thermal element.
- **Fan control:** PWM fan output, tachometer feedback where supported, fan fault detection where practical, and interface to enclosure ventilation/heat-rejection logic.
- **Temperature sensing:** Thermistor, RTD, thermocouple, digital temperature sensor, or equivalent front end; signal conditioning, filtering, calibration allowance, and sensor-fault detection.
- **Power monitoring:** Voltage/current monitoring on selected input, logic, sensor, actuator, and thermal-control rails for bring-up, fault detection, and service diagnostics.
- **Power and protection design:** Low-voltage DC input architecture with regulated logic/sensor/actuator rails, fusing or resettable protection where appropriate, reverse/transient protection, inrush consideration, local decoupling, power sequencing where required, and safe output defaults on reset or power loss.

- **Communication interface:** USB, UART-over-USB, RS-485, Ethernet, or equivalent compute-to-control link for commands, thermal status, actuator status, firmware version, fault state, service-mode operation, and diagnostic logging.
- **PCB EMC/ESD design:** Ground partitioning, short high-current loops, controlled return paths, connector-level TVS protection, input filtering, shield/chassis termination points, separation of noisy actuator circuits from analog sensor circuits, and layout practices aligned with IEC 61326-1 / IEC 60601-1-2 / IEC 61000-4-x pre-compliance expectations.
- **Physical PCB implementation:** Connector placement matched to harness routing, keyed/locking connectors where practical, labeled test points, programming header, revision marking, mounting holes, service access, rework allowance, and manufacturability suitable for Rev A bring-up and Rev B refinement.
 - Rev A: functional bring-up;
 - Rev B: refinement for grounding, shielding, connectorization, ESD robustness, serviceability, and manufacturability;
- **High-speed interface boundary:** instrument cameras, translation stage controllers, and other high-bandwidth commercial peripherals connected directly to the compute platform where practical, avoiding unnecessary USB3/high-speed routing through the custom PCB.

Firmware: Firmware for the control PCB or electronics assembly is specified as:

- **Firmware architecture:** Modular embedded firmware with hardware-abstraction layers, subsystem drivers, configuration storage, diagnostic routines, and deterministic state-machine handling for startup, idle, active control, fault, service, and shutdown states.
- **Hardware-control functions:** Power-up initialization, sensor acquisition, thermal-control loop, illumination control, fan/actuator control, default output states, actuator limits, and service-readable firmware/version information.
- **Fault handling:** Sensor-fault detection, over-temperature response, actuator fault handling, power-good fault handling where supported, watchdog recovery, safe output defaults, fault latching where appropriate, and service-readable fault codes.
- **Service and diagnostics:** Command/status interface for bench testing and service, including temperature readings, actuator states, illumination state, fan state, fault state, configuration values, firmware version, and basic diagnostic logs.
- **Firmware security:** Controlled firmware image management, checksum or signature verification, debug-interface control, configuration-write protection, and restriction of unintended service-command access during normal operation.
- **Firmware upgrade:** Defined update path through USB, bootloader, programming header, or equivalent service interface; revision tracking, recovery/rollback consideration where practical, and update procedure suitable for service.

- **Documentation and traceability:** Source-code organization, version control, build notes, command/interface documentation, state-machine description, and traceability to assigned hardware-control functions sufficient for documentation and regulatory expansion.

Power distribution, grounding, shielding, and cabling: The instrument shall include a compliance-test-ready power, grounding, shielding, and cabling architecture designed to support formal EMC, ESD, electrical-safety, and pre-compliance evaluation under the applicable standards pathway, including IEC 60601-1, IEC 60601-1-2, IEC 61326-1, and IEC 61000-4-x test methods as determined by the final regulatory strategy.

- **Power architecture:** Certified off-the-shelf AC/DC supply, external medical-grade/laboratory-grade adapter selected for target-standard compatibility, leakage-current considerations, thermal load, derating, availability, serviceability, and integration with the instrument enclosure.
- **DC distribution:** Low-voltage DC rail architecture for control electronics, illumination, fans, thermal-control elements, sensors, service interfaces, and auxiliary loads; documented rail voltages, current budgets, connector assignments, and load-segregation strategy.
- **Protection and safety circuits:** Input fusing or resettable overcurrent protection, reverse/transient protection, inrush control where required, power-good monitoring where practical, safe output defaults, and controlled behavior during startup, shutdown, reset, brownout, and power loss.
- **Grounding architecture:** Defined protective earth strategy, chassis ground, signal ground, shield termination points, compute/control grounding interface, equipotential bonding where required, and documented grounding-continuity verification.
- **EMC segregation:** Physical and electrical separation of high-current, switching, motor, TEC/heater, LED-driver, fan, and compute power paths from camera, sensor, analog, communication, and control-signal paths.
- **Shielding and filtering:** Shielded cable selection where required, connector-level shield termination, chassis-entry treatment, ferrites or common-mode chokes where appropriate, input/output filtering, TVS/ESD protection, and controlled return paths for radiated and conducted emissions reduction.
- **Harnessing and routing:** Labeled harnesses, keyed/locking connectors where practical, strain relief, bend-radius control, service-loop allowance, moving-stage cable management, and routing away from optical aperture, cartridge-removal path, thermal elements, and sensitive sensor wiring.
- **Compliance-test preparation:** Design provisions addressing IEC 60601-1-2 / IEC 61326-1 EMC phenomena, including electrostatic discharge, radiated emissions, conducted emissions, radiated immunity, EFT/burst, surge, conducted immunity, voltage dips/interruptions, and power-frequency magnetic-field susceptibility where applicable.

Mechanical design and enclosure: The mechanical design shall define the structural, safety, usability, thermal, EMC, and service architecture of the instrument as a medical-device hardware platform intended to proceed into compliance testing.

- **Subsystems supported:** Controlled datums for optical stack, motion stages, cartridge tray, thermal hardware, control PCB, compute platform, grounding points, shield terminations, and harnessing.
- **Mechanical safety:** Tip/slide stability, sharp-edge control, pinch-point control, service-panel control, strain relief, and user-access separation from energized, heated, or moving assemblies; IEC 60601-1 awareness.
- **Usability engineering:** IEC 62366-1-informed cartridge access, minimized operator-dependent alignment, visible status/indicator zones, connector differentiation, insertion guidance, and foreseeable-use-error reduction.
- **Thermal and airflow design:** Compute/power heat segregation, illumination heat management, cartridge-region thermal-control support, airflow path definition, and user-accessible surface-temperature control.
- **EMC/ESD enclosure provisions:** Enclosure seams, cable-entry points, shield-contact regions, chassis bonding points, access-panel grounding, conductive coatings/gaskets where required, and controlled conductive/insulating transitions for IEC 60601-1-2 / IEC 61326-1 / IEC 61000-4-x testing.
- **Ingress, cleaning, and serviceability:** IEC 60529-informed finger-access and spray/splash ingress protection (IP 44 design target); ISO 17664-1-informed wipeable surfaces and cleaning-agent compatibility; cartridge-access geometry, inspection access, and replacement access for serviceable modules.

Human interface and service interface: The system shall include only the local indicators, buttons, display elements, or service-control interfaces required to operate and test the hardware, and a 5.5" touch screen interface to be used for the UiT developed clinical work flow. The system may include a basic service interface running on the compute platform or connected development computer for stage motion, illumination, thermal status, fault status, and diagnostic commands.

The hardware interface shall support:

- **Power status:** Local indication of energized, standby, or off state.
- **Fault status:** Visible indication of active or latched hardware faults.
- **Thermal status:** Display or indicator for temperature-control state.
- **Service control:** Restricted access to hardware service-mode functions.
- **Diagnostic access:** Retrieval of sensor, actuator, firmware, and fault data.
- **Safe disable:** Controlled shutdown or disablement of active hardware functions.

- **RFID/barcode scanner:** to read a unique identifier associated with each cartridge.

3.3 Compliance needs

Compliance testing and documentation related to the following standards/frameworks have to be undertaken. Note that the compliance documents have to be made according to the recommendation and templates of our regulatory compliance expert (another 3rd party subcontract) on the project. Interface and communication with the regulatory contractor will be done after signing the contract.

Standard / Framework	Scope	Supplier's Responsibility
ISO 13485	QMS, design controls, traceability, controlled design outputs	ISO 13485-aligned hardware development; BOM, CAD, schematics, firmware records, verification records, change history
ISO 14971	Risk management	Support hazard analysis, risk controls, risk-control verification, hardware risk inputs
IEC 60601-1	Electrical safety	IEC 60601-1-aligned architecture; grounding, enclosure safety, fault-condition design, test readiness
IEC 60601-1-2	EMC: emissions and immunity	EMC-aware PCB, cabling, grounding, shielding, enclosure seams, cable entry, power architecture
IEC 61000-4-x	ESD, EFT/burst, surge, conducted/radiated immunity, dips/interruptions, magnetic fields	TVS, filtering, shielding, grounding, cable routing, power-entry design for relevant immunity phenomena
IEC 62366-1	Usability engineering and use-related risk	Hardware usability inputs: cartridge insertion, indicators, connector differentiation, service access, fault visibility
IEC 62304	Medical-device software lifecycle for embedded firmware/software	Firmware versioning, state-machine documentation, command interface, traceability, controlled source records
IEC 81001-5-1 / FDA Cybersecurity Guidance	Secure health software engineering, cybersecurity risk management	Firmware security controls: update path, debug control, configuration protection, service-command control
IEC 62471	Photobiological safety for lamps/LED systems	Illumination selection/integration with intensity, wavelength, exposure, shielding, labeling inputs
IEC 60529	Enclosure ingress protection against solids/water	IP44-oriented enclosure design where compatible with optics, airflow, cartridge access, service
IEC 60068	Environmental robustness: shock, vibration, thermal cycling, humidity	Robustness-aware mechanical/electrical design; internal checks; test-readiness evidence

ISO 17664-1	Cleaning, disinfection, wipeability instructions	Material and exposed-surface inputs; wipeability features; cleaning-agent compatibility support
ISO 15223-1 / ISO 20417	Symbols, labeling, IFU, warnings, markings	Hardware labels, connector labels, caution markings, service labels, device ID inputs

3.4 Deliverables

- A. **Prototypes:** The supplier needs to ship two working prototypes at Rev 1 (Deliverable A-1, end of month 3, expected) for user testing and feedback and at Rev 2 (month 6) as one of the final deliverables. These may be returned to the supplier if needed for reuse of components or upgrading them for the Rev 2 (Deliverable A-2, end of month 6).
Costs of shipping from supplier to UiT should be included in the contract and should be borne by the supplier thereafter. Costs of shipping from UiT to the supplier will be incorporated in the offer and borne by the supplier. Shipping both directions should be done according to DDP (Incoterms 2020). Shipping from UiT to supplier should, if possible, be done with the same packaging as from supplier to UiT.
- B. **Complete design documentation package,** sufficient to support design review, controlled small batch reproduction, compliance-test preparation, and UiT-controlled design history file incorporation, including:
- system architecture and subsystem block diagrams;
 - mechanical CAD package, fabrication drawings, and export files;
 - electrical schematics, PCB layout files, fabrication outputs, assembly files, and PCB revision records;
 - system BOM identifying major components, off-the-shelf modules, custom parts, and commercially available replacements where applicable;
 - wiring diagrams, harness list, connector list, grounding/shielding notes, and cable-routing documentation;
 - firmware architecture documentation, firmware-command/interface documentation, state-machine description, version records, and build notes;
 - assembly procedure, service notes, inspection points, configuration records, known-issues log, deviations register, assumptions register, and UiT's dependency register;
 - as-built configuration records for each delivered unit, including serial/unit identifier, hardware revisions, firmware version, compute configuration, installed components, deviations, and accepted exceptions.
- C. **Design verification and test evidence package,** aligned to Design Verification Matrix proposed by the supplier, including completed internal verification records for each required verification test.
- D. **Compliance-support documentation package,** suitable for UiT-controlled regulatory, QMS, and test-lab activities, including:
- standards identified in the table above;

- hardware-level requirements traceability matrix linking system requirements to design outputs and verification evidence
 - risk-control evidence for hardware-level design controls;
 - EMC/ESD, grounding, shielding, electrical-safety, usability, ingress, wipeability, material-selection, and labeling;
 - compliance-test configuration summary for external IEC 60601-1 / IEC 60601-1-2 or other applicable medical-device test-lab engagement by UiT;
 - documented deviations, limitations, and unresolved UiT-controlled dependencies affecting compliance-test readiness.
- E. **Draft labeling and user documentation**, limited to hardware operation, service access, safety markings, and compliance-test configuration, including:
- draft hardware labeling inputs, connector labels, caution markings, service labels, device identification markings, and status indicator descriptions;
 - draft hardware-use instructions for power-up, cartridge insertion/removal, service-mode access, safe disable/shutdown, and basic troubleshooting;
 - draft service instructions for hardware diagnostics, firmware version check, thermal-control check, illumination check, motion check, and fault-state review;
 - draft cleaning and wipeability inputs for exposed hardware surfaces, subject to UiT-defined cleaning workflow and validation;
 - draft warnings, precautions, and limitations related to hardware operation, service access, heated surfaces, moving components, electrical interfaces, and cartridge-interface handling.
- F. **Firmware repository**, containing the source materials developed by Supplier for instrument hardware control, in the form of a private GitHub repository.

4 Requirements for documentation, information etc.

Design Verification Matrix (to be included in the proposal): The supplier is supposed to include in the proposal a design verification matrix in order to develop an outline of evidence of the design meeting the requirements and being achieved in practice. They also need to outline the criteria for accepting the verification outcome.

Time plan and mandatory milestones (to be included in the proposal): Supplier also needs to include a time plan with at least three milestones (also tagged to milestone payments) listed below:

1. Sub-system design and productionization readiness (end of week 6, expected) – this should include sharing of initial versions of production designs of all the sub-systems and discussion on whether they meet the design and function expectations
2. Rev 1 prototypes delivery (end of month 3, expected) – this is marked by UiT receiving 2 Rev 1 prototypes and performing a first successful run on-site.

3. End of the project – this is marked by delivery of all the deliverables and performing a first successful run onsite, and UiT assessing all the deliverables as acceptable.

The supplier is free to include more milestones (which will not be tagged to payments) and recommended to propose a detailed time plan including explicit inputs from UiT.

As a part of the contract: Supplier needs to deliver documents listed as Deliverables B-E in addition to prototypes listed in deliverable A. Additional documents and information may be requested as part of compliance needs, and must be provided by the supplier as requested, available, and feasible.

As a part of the contract: UiT will be responsible for:

- Providing all relevant and available technical inputs including design logic, precise interface and control details of hardware-microfluidic chip interaction, software, signal control logic and synchronization details, report generation and user interaction logic, etc.
- Feedback on intermediate designs, user experience with intermediate prototypes, reports of functional tests done on site at UiT or its clinical partners, etc.
- All the compliance documentations beside those stated above or those that need information/inputs from the supplier. For those that need information/inputs from the supplier, the suppliers need to provide the information as requested and available.

5 Training

If needed, remote or on site training of the staff regarding the use, maintenance, trouble shooting, assembly/integration, testing, functional verification etc. is expected. Remote training is preferred for environmental and climate considerations. For on site training, travel costs can be discussed but are not expected to be covered by the supplier by default within the contract.

6 Table of requirements

The requirements in the table of requirements form the basis for the Supplier's description of its solution specification, cf. Appendix 2. The Supplier must give an extensive description of all requirements so that the Parties will have a common understanding of what is to be delivered, or which can give the Buyer alternative perspectives to the requirements expressed in the Buyer's requirements specification.

The different requirements have different priority.

Priority A = Eligibility criteria for the suppliers (all of these should be satisfied).

Priority B = Preference will be given to suppliers who can provide best according to these criteria.

When filling out the table of requirements the Supplier shall mark an (X) in the column for yes, partly or no under “the Supplier’s fulfilment”. Reference to relevant documentation and any additional comments shall be made in the column “Comment”. It is reminded that it is the duty of the Supplier to document that it fulfils the set requirements. Any missing documentation will result in the requirement being considered as not fulfilled.

No.	Priority	Description
		Absolute requirements
	A	Technical experience of the company or the team members with optical, optomechanical, thermal and electric/electronic and firmware/design and prototyping Please provide CV of team members, pictures or names or relevant non-confidential details of previous projects demonstrating relevant certifications, or other general evidence.
	A	Design and prototyping experience of the company or the team members in developing medtech devices/instruments Please provide CV of team members, pictures or names or relevant non-confidential details of previous projects demonstrating relevant certifications, or other general evidence.
	A	Experience of the company or the team members of making compliance documents related to medtech devices with electrical components Please provide CV of team members, pictures or names or relevant non-confidential details of previous projects demonstrating, relevant certifications/clearances, example compliance documentations, or other general evidence
	A	Experience of the company or the team members regarding usability engineering Please provide CV of team members, pictures or names or relevant non-confidential details of previous projects demonstrating, relevant certifications/clearances, example compliance documentations, or other general evidence

	A	Ability to deliver all the deliverables listed in section 3.4
	A	The service should be delivered in at least three milestones (tagged to payments) listed in Section 3.
	A	After each milestone and concurrent payment of invoice, UiT receive ownership over the products in their current state.
	A	The project is financed by EIC (Europe Innovations Council). Legal entities established in China are not eligible to participate in Horizon Europe Innovation Actions. This includes participation as beneficiaries, affiliated entities, associated partners, third parties giving in-kind contributions, subcontractors or recipients of financial support to third parties (if any). Please confirm non-involvement from legal entities established in China.
	A	All IP (Intellectual property) resulting from the project belongs to UiT
		Technical and functional criteria
	B	Experience of devices that need consumables for operations Please provide pictures or names or relevant non-confidential details of previous projects demonstrating, or other general evidence
	B	Experience of devices around fluidic/microfluidic components Please provide CV of team members, pictures or names or relevant non-confidential details of previous projects demonstrating, or other general evidence.
	B	Suppliers will be evaluated based on their understanding of the project. Points will be given to suppliers who can prove credibility in their proposals for time plan, in allegiance with our design requirements, deliverables and compliance needs. The supplier's understanding of the project is considered very important.
		Environmental criteria
	B	Reducing carbon footprint of operations, meetings, travels, and/or shipping. Please provide documentation, certificates, or other relevant form of evidences of commitment
	B	Use of sustainable or low carbon energy source.

		Please provide documentation, certificates, or other relevant form of evidences of commitment
	B	Other measures to positively impact climate and environmental factors. Please provide reasoning and documentation