

## Request for Proposals (RFP)

# CE Mark Certification of the Umbiflow (continuouswave foetal ultrasound) Medical Device, EU Class II-a to the CSIR

## RFP No. 1117.1/03/11/2023

| Date of Issue  | Monday, 16 October 2023   |                           |  |  |
|--|---|---------------------------|--|--|
| Enquiries  | Strategic<br>Procurement<br>Unit  | E-mail: tender@csir.co.za |  |  |
|  | Please use RFP No and RFP Description as subject reference                        |                           |  |  |
| Last date for submission of enquiries/clarifications | Friday, 20 October 2023 at 16H30  |                           |  |  |
| Electronical Submission                              | tender@csir.co.za (If tender submission exceeds 25MB multiple emails can be sent) |                           |  |  |
| CSIR business hours                                  | 08h00 – 16h30   |                           |  |  |
| Category   | Professional Serv   | rices                     |  |  |
| Closing Date and Time                                | Friday, 03 November 2023 at 16H30   |                           |  |  |

## **TABLE OF CONTENTS**

| SE  | CT  |   | NI | Λ                |
|-----|-----|---|----|------------------|
| oe. | C I | w | IV | $\boldsymbol{H}$ |

| GENE  | RAL RFP TERMS AND CONDITIONS   | 4        |
|-------|--|----------|
| 1     | INTRODUCTION   | 4        |
| 2     | SUBMISSION OF PROPOSALS  | 4        |
| 3     | COUNTER CONDITIONS   | 5        |
| 4     | FRONTING   | 5        |
| 5     | PRICING PROPOSAL   | 6        |
| 6     | APPOINTMENT OF SERVICE PROVIDER  | 6        |
| 7     | ENQUIRIES AND CONTACT WITH THE CSIR  | 7        |
| 8     | MEDIUM OF COMMUNICATION  | 7        |
| 9     | CORRECTNESS OF RESPONSES   | 7        |
| 10    | VERIFICATION OF DOCUMENTS  | 7        |
| 11    | RESPONSIBILITY FOR SUB-CONTRACTORS AND BIDDER'S PERSONNEL  | 8        |
| 12    | ADDITIONAL TERMS AND CONDITIONS  | 8        |
| 13    | SPECIAL CONDITIONS   | 9        |
| 14    | CONFLICT OF INTEREST, CORRUPTION AND FRAUD   | 10       |
| 15    | MISREPRESENTATION DURING THE LIFECYCLE OF THE CONTRACT   | 11       |
| 16    | PREPARATION COSTS AND LIMITATION OF LIABILITY  | 11       |
| 17    | INDEMNITY  | 11       |
| 18    | PRECEDENCE   | 12       |
| 19    | TAX COMPLIANCE   | 12       |
| 20    | TENDER DEFAULTERS AND RESTRICTED SUPPLIERS   | 12       |
| 21    | GOVERNING LAW  | 12       |
| 22    | CONFIDENTIALITY  | 13       |
| 23    | AVAILABILITY OF FUNDS  | 13       |
| 24    | PERSONAL INFORMATION   | 13       |
| 25    | DISCLAIMER   | 14       |
| SECTI | ON B   | 15       |
| EVAL  | JATION METHODOLOGY   | 15       |
| 26    | EVALUATION CRITERIA  | 15       |
| 27    | OBJECTIVE CRITERIA   | 16       |
| 28    | NATIONAL TREASURY CENTRAL SUPPLIER DATABASE (CSD) REGISTRATIONAL SUPPLIER | ON<br>17 |

Request for Proposal CSIR RFP No.: 1117.1/03/11/2023 Page 2 of 49

## RFP STRUCTURE

SECTION A: GENERAL RFP TERMS AND CONDITIONS SECTION B: EVALUATION METHODOLOGY / PROCESS

## LIST OF ANNEXURES

- Annexure A Standard Bidding Document (SBD) 1 Form
- Annexure B Technical Specification
- Annexure C Technical Evaluation Matrix/Rubrics
- Annexure D Pricing Schedule
- Annexure E Proposal Form and List of Returnable Documents
- Annexure F Certificate of Acquaintance with RFP
- Annexure G Preference Point Award Form
- Annexure H– RFP Clarification Request Form
- Annexure I

  Standard Bidding Document (SBD) 4 Form
- Annexure J RFP Declaration and Breach of Law Form
- Annexure K Mutual Non-Disclosure Agreement

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **3** of **49** 

**SECTION A** 

**GENERAL RFP TERMS AND CONDITIONS** 

1 INTRODUCTION

The Council for Scientific and Industrial Research (CSIR) is one of the leading scientific

research and technology development organisations in Africa. In partnership with national and

international research and technology institutions, the CSIR undertakes directed and

multidisciplinary research and technology innovation that contributes to the improvement of

the quality of life of South Africans. The CSIR's main site is in Pretoria while it is represented

in other provinces of South Africa through regional offices.

2 SUBMISSION OF PROPOSALS

2.1 All proposals are to be submitted electronically to tender@csir.co.za. No late proposals

will be accepted.

2.2 All proposals will only be considered if received by the CSIR before the closing date and

time (as indicated on the cover page). The CSIR business hours are between 08h00 and

16h30.

2.3 All proposal submissions are to be clearly subject-referenced with the RFP number and

**RFP Description**. Proposals must consist of two parts, each of which must be sent in two

separate emails with the following subject:

PART 1: Technical Proposal (Please indicated the RFP Number on each File/folder)

PART 2: Pricing Proposal, Specific Goals claim documentation: RFP No.: (Please

indicate the RFP Number on each File/folder)

2.4 Proposals submitted must be signed by a person or persons duly authorised.

2.5 Proposals submitted at incorrect location and/or address, will not be accepted for

consideration and, where practicable, will be returned unopened to the Bidder(s).

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **4** of **49** 

2.6 Proposals received after the closing date and time, at the address indicated in the bid

documents, will not be accepted for consideration and, where practicable, will be returned

unopened to the Bidder(s).

2.7 All dates and times in this bid are South African standard time.

2.8 Any time or date in this bid is subject to change at the CSIR's discretion. The establishment

of a time or date in this bid does not create an obligation on the part of the CSIR to take any

action or create any right in any way for any bidder to demand that any action be taken on

the date established. The bidder accepts that, if the CSIR extends the deadline for bid

submission (the Closing Date) for any reason, the requirements of this bid otherwise apply

equally to the extended deadline.

2.9 Documents submitted via cloud solutions such as: WeTransfer, Google Drive, Dropbox, etc.

will not be considered.

2.10 The naming / labelling syntax of files or documents must be short and simple.

2.11 The CSIR will award the contract to qualified bidder(s)' whose proposal is determined to be

the most advantageous to the CSIR, taking into consideration the technical (functional)

solution, price, specific goals and objective criteria.

3 COUNTER CONDITIONS

Bidders' attention is drawn to the fact that amendments to any of the RFP Conditions or

setting of counter conditions by Bidders or qualifying any RFP Conditions will result in the

invalidation of such bids.

4 FRONTING

4.1 Government supports the spirit of broad based black economic empowerment and

recognizes that real empowerment can only be achieved through individuals and

businesses conducting themselves in accordance with the Constitution and in an honest,

fair, equitable, transparent and legally compliant manner. Against this background the

Government condemns any form of fronting.

4.2 The Government, in ensuring that Bidders conduct themselves in an honest manner will, as part of the RFP evaluation processes, conduct or initiate the necessary enquiries/investigations to determine the accuracy of the representation made in bid documents. Should any of the fronting indicators as contained in the Guidelines on Complex Structures and Transactions and Fronting, issued by the Department of Trade and Industry, be established during such enquiry / investigation, the onus will be on the Bidder / contractor to prove that fronting does not exist. Failure to do so within a period of 14 days from date of notification may invalidate the bid / contract and may also result in the restriction of the Bidder / contractor to conduct business with the public sector for a period not exceeding ten years, in addition to any other remedies the CSIR may have against the Bidder / contractor concerned.

## 5 PRICING PROPOSAL

- 5.1 Pricing must be provided in South African Rand (including all applicable taxes less all unconditional discounts).
- 5.2 Prices that are subject to escalation and exchange rate fluctuations are to be clearly indicated, with the currency and ROE used in the quotation must be clearly indicated.
- 5.3 Price should include additional cost elements such as travel cost, freight, insurance until acceptance, duty where applicable, etc.
- 5.4 Payment will be according to the CSIR Payment Terms and Conditions (Link).
- 5.5 Please provide a detail pricing using a Pricing Schedule/Bill of Quantities outlined under Annexure D. Pricing must strictly be in accordance with the Pricing Schedule.

### 6 APPOINTMENT OF SERVICE PROVIDER

- 6.1 The contract will be awarded to the bidder who scores the highest total number of points during the evaluation process, except where the law permits otherwise.
- 6.2 Appointment as a successful service provider shall be subject to the parties agreeing to mutually acceptable contractual terms and conditions. In the event of the parties failing to reach such agreement, CSIR reserves the right to appoint an alternative supplier.

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **6** of **49** 

6.3 Awarding of contracts will be published on the same platform where the bid was published,

and no regret letters will be sent to unsuccessful bidders.

7 ENQUIRIES AND CONTACT WITH THE CSIR

Any enquiry regarding this RFP shall be submitted in writing to CSIR to the email and format

outlined in the table on cover page of this RFP document.

Any other contact with CSIR personnel involved in this tender is not permitted during the

RFP process other than as required through existing service arrangements or as requested

by the CSIR as part of the RFP process.

8 MEDIUM OF COMMUNICATION

All documentation submitted in response to this RFP must be in English.

9 CORRECTNESS OF RESPONSES

9.1 The bidder must confirm satisfaction regarding the correctness and validity of their proposal

and that all prices and rates quoted cover all the work/items specified in the RFP. The

prices and rates quoted must cover all obligations under any resulting contract.

9.2 The bidder accepts that any mistakes regarding prices and calculations will be at their own

risk.

10 VERIFICATION OF DOCUMENTS

10.1 Bidders should check the numbers of the pages to satisfy themselves that none is missing

or duplicated. No liability will be accepted by the CSIR in regard to anything arising from the

fact that pages are missing or duplicated.

10.2 Pricing schedule and specific goals credentials should be submitted with the proposal, but

as a separate document and no such information should be available in the technical

proposal.

11 RESPONSIBILITY FOR SUB-CONTRACTORS AND BIDDER'S PERSONNEL

A bidder is responsible for ensuring that its personnel (including agents, officers, directors,

employees, advisors and other representatives), its sub-contractors (if any) and personnel

of its sub-contractors comply with all terms and conditions of this bid. In the event that the

CSIR allows a bidder to make use of sub-contractors, such sub-contractors will at all times

remain the responsibility of the bidder and the CSIR will not under any circumstances be

liable for any losses or damages incurred by or caused by such sub-contractors.

12 ADDITIONAL TERMS AND CONDITIONS

12.1 A bidder shall not assume that information and/or documents supplied to CSIR, at any time

prior to this request, are still available to CSIR, and shall consequently not make any

reference to such information document in its response to this request.

12.2 Copies of any affiliations, memberships and/or accreditations that support your submission

must be included in the tender.

12.3 In case of proposal/s from a joint venture, the following must be submitted together with the

proposal/s:

A joint venture agreement signed by both parties clearly indication the lead partner,

including split of work;

The Tax Compliance Status (TCS) or CSD Report of each joint venture partner;

Proof of ownership/shareholder certificates/copies; and

Company registration certificate/s.

12.4 An omission to disclose material information, a factual inaccuracy, and/or a

misrepresentation of fact may result in the disqualification of a tender, or cancellation of any

subsequent contract.

12.5 Failure to comply with any of the terms and conditions as set out in this document will

invalidate the Proposal.

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page 8 of 49

13 SPECIAL CONDITIONS

The CSIR reserves the right to:

13.1 Extend the closing date of this RFP;

13.2 Correct any mistakes at any stage of the tender that may have been in the Bid documents

or occurred at any stage of the tender process;

13.3 Verify any information contained in the bidder's submission;

13.4 Request documentary proof regarding the bidder's submission;

13.5 Carry out site inspections, product evaluations or explanatory meetings in order to verify

the nature and quality of the product/service offered by the bidder(s) or verify any

information whether before or after the adjudication of this RFP;

13.6 Award this tender to a bidder that did not score the highest total number of points, only in

accordance with Section 2(1)(f) of the PPPFA (Act 5 of 2000);

13.7 Request audited financial statements or other documents for the purpose of a due diligence

exercise to determine if the bidder will be able to execute the contract:

13.8 Award this RFP as a whole or in part;

13.9 Award this RFP to multiple bidders;

13.10 Cancel and/or terminate the tender process at any stage, including after the Closing Date

and/or after presentations have been made, and/or after tenders have been evaluated

and/or after the preferred bidder(s) have been notified of their status as such;

13.11 Post tender negotiate on any elements on the bid, including but not limited to technical,

transformation, price, and contractual terms and conditions.;

13.12 Not to award a contract to a bidder who is associated with a security breach that materially

adversely affects other entities or if any directors or officers of a bidder are formally accused

of fraudulent or illegal conduct which, would harm the CSIR's reputation by its continued

association with the bidder.

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **9** of **49** 

## 14 CONFLICT OF INTEREST, CORRUPTION AND FRAUD

- 14.1 The CSIR reserves its right to disqualify any bidder who either itself or any of whose members (save for such members who hold a minority interest in the bidder through shares listed on any recognised stock exchange), indirect members (being any person or entity who indirectly holds at least a 15% interest in the bidder other than in the context of shares listed on a recognised stock exchange), directors or members of senior management, whether in respect of CSIR or any other government organ or entity and whether from the Republic of South Africa or otherwise ("Government Entity")
  - engages in any collusive tendering, anti-competitive conduct, or any other similar conduct, including but not limited to any collusion with any other bidder in respect of the subject matter of this bid;
  - b. seeks any assistance, other than assistance officially provided by a Government Entity, from any employee, advisor or other representative of a Government Entity in order to obtain any unlawful advantage in relation to procurement or services provided or to be provided to a Government Entity;
  - c. makes or offers any gift, gratuity, anything of any value or other inducement, to any Government Entity's officers, directors, employees, advisors or other representatives in order to obtain any unlawful advantage in relation to procurement or services provided or to be provided to a Government Entity;
  - accepts anything of value or an inducement that would or may provide financial gain, advantage or benefit in relation to procurement or services provided or to be provided to a Government Entity;
  - e. pays or agrees to pay to any person any fee, commission, percentage, brokerage fee, gift or any other consideration, that is contingent upon or results from, the award of any tender, contract, right or entitlement which is in any way related to procurement or the rendering of any services to a Government Entity;
  - f. has in the past engaged in any matter referred to above; or
  - g. has been found guilty in a court of law on charges of fraud and/or forgery, regardless of whether or not a prison term was imposed and despite such bidder, member or director's name not specifically appearing on the List of Tender Defaulters kept at National Treasury.

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **10** of **49** 

15 MISREPRESENTATION DURING THE LIFECYCLE OF THE CONTRACT

15.1 The bidder should note that the terms of its Tender will be incorporated in the proposed

contract by reference and that the CSIR relies upon the bidder's Tender as a material

representation in making an award to a successful bidder and in concluding an agreement

with the bidder.

15.2 It follows therefore that misrepresentations in a Tender may give rise to service termination

and a claim by the CSIR against the bidder notwithstanding the conclusion of the Service

Level Agreement between the CSIR and the bidder for the provision of the Service in

question. In the event of a conflict between the bidder's proposal and the Service Level

Agreement concluded between the parties, the Service Level Agreement will prevail.

16 PREPARATION COSTS AND LIMITATION OF LIABILITY

The Bidder will bear all its costs in preparing, submitting and presenting any response or

Tender to this bid and all other costs incurred by it throughout the bid process. Furthermore,

no statement in this bid will be construed as placing the CSIR, its employees or agents

under any obligation whatsoever, including in respect of costs, expenses or losses incurred

by the bidder(s) in the preparation of their response to this bid.

A bidder participates in this bid process entirely at its own risk and cost. The CSIR shall not

be liable to compensate a bidder on any grounds whatsoever for any costs incurred or any

damages suffered as a result of the Bidder's participation in this Bid process.

17 INDEMNITY

If a bidder breaches the conditions of this bid and, as a result of that breach, the CSIR incurs

costs or damages (including, without limitation, the cost of any investigations, procedural

impairment, repetition of all or part of the bid process and/or enforcement of intellectual

property rights or confidentiality obligations), then the bidder indemnifies and holds the

CSIR harmless from any and all such costs which the CSIR may incur and for any damages

or losses the CSIR may suffer.

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **11** of **49** 

18 PRECEDENCE

This document will prevail over any information provided during any briefing session

whether oral or written, unless such written information provided, expressly amends this

document by reference.

19 TAX COMPLIANCE

No tender shall be awarded to a bidder who is not tax compliant. The CSIR reserves the

right to withdraw an award made, or cancel a contract concluded with a successful bidder

in the event that it is established that such bidder was in fact not tax compliant at the time

of the award or has submitted a fraudulent Tax Clearance Certificate to the CSIR, or whose

verification against the Central Supplier Database (CSD) proves non-compliant. The CSIR

further reserves the right to cancel a contract with a successful bidder in the event that such

bidder does not remain tax compliant for the full term of the contract.

20 TENDER DEFAULTERS AND RESTRICTED SUPPLIERS

No tender shall be awarded to a bidder whose name (or any of its members, directors,

partners or trustees) appear on the Register of Tender Defaulters kept by National Treasury,

or who have been placed on National Treasury's List of Restricted Suppliers. The CSIR

reserves the right to withdraw an award, or cancel a contract concluded with a Bidder should

it be established, at any time, that a bidder has been blacklisted with National Treasury by

another government institution.

21 GOVERNING LAW

South African law governs this bid and the bid response process. The bidder agrees to

submit to the exclusive jurisdiction of the South African courts in any dispute of any kind

that may arise out of or in connection with the subject matter of this bid, the bid itself and all

processes associated with the bid.

22 CONFIDENTIALITY

Except as may be required by operation of law, by a court or by a regulatory authority having

appropriate jurisdiction, no information contained in or relating to this bid or a bidder's

tender(s) will be disclosed by any bidder or other person not officially involved with the

CSIR's examination and evaluation of a Tender.

No part of the bid may be distributed, reproduced, stored or transmitted, in any form or by

any means, electronic, photocopying, recording or otherwise, in whole or in part except for

the purpose of preparing a Tender. This bid and any other documents supplied by the CSIR

remain proprietary to the CSIR and must be promptly returned to the CSIR upon request

together with all copies, electronic versions, excerpts or summaries thereof or work derived

there from.

Throughout this bid process and thereafter, bidder(s) must secure the CSIR's written

approval prior to the release of any information that pertains to (i) the potential work or

activities to which this bid relates; or (ii) the process which follows this bid. Failure to adhere

to this requirement may result in disqualification from the bid process and civil action.

23 AVAILABILITY OF FUNDS

Should funds no longer be available to pay for the execution of the responsibilities of this

bid, the CSIR may terminate the Agreement at its own discretion or temporarily suspend all

or part of the services by notice to the successful bidder who shall immediately make

arrangements to stop the performance of the services and minimize further expenditure:

Provided that the successful bidder shall thereupon be entitled to payment in full for the

services delivered, up to the date of cancellation or suspension.

24 PERSONAL INFORMATION

24.1 Each Party consents to the other Party holding and processing "personal information" (as

defined in the POPI Act) relating to it for legal, personnel, administrative and management

purposes (including, if applicable, any "special personal information" relating to him/her, as

defined in the POPI Act). Notwithstanding the generality of the aforesaid, each Party hereby

------g .... g ....

undertakes to comply with all relevant provisions of the POPI Act and any other applicable

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023

Page 13 of 49

data protection laws. The bidder further agrees to comply with all CSIR's reasonable internal

governance requirements pertaining to data protection.

24.2 Each Party consents to the other Party making such information available to those who

provide products or services to such parties (such as advisers, regulatory authorities,

governmental or quasi-governmental organisations and potential purchasers of such Party

or any part of their business).

24.3 While performing any activity where a Party is handling personal information as a

"responsible party" (as defined in the POPI Act), each Party undertakes that it will process

the personal information strictly in accordance with the terms of the POPI Act, this Contract,

and the other Party's instructions from time to time, and take appropriate operational

measures to safeguard the data against any unauthorised access.

24.4 Each Party acknowledges that in the course of conducting business with each other, each

Party intends to maintain and process personal information about the other Party in an

internal database. By signing this Contract, each Party consents to the maintenance and

processing of such personal information.

Where relevant, the bidder shall procure that all of its personnel, agents, representatives,

contractors, sub-contractors and mandataries shall comply with the provisions of this clause

30 (Personal Information). The CSIR shall be entitled on reasonable notice to conduct an

inspection or audit bidders compliance with the requisite POPI Act safeguards.

25 DISCLAIMER

This RFP is a request for proposals only and not an offer document. Answers to this RFP

must not be construed as acceptance of an offer or imply the existence of a contract

between the parties. By submission of its proposal, bidders shall be deemed to have

satisfied themselves with and to have accepted all Terms & Conditions of this RFP. The

CSIR makes no representation, warranty, assurance, guarantee or endorsements to bidder

concerning the RFP, whether with regard to its accuracy, completeness or otherwise and

the CSIR shall have no liability towards the bidder or any other party in connection therewith.

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023

Page **14** of **49** 

### **SECTION B**

## **EVALUATION METHODOLOGY**

#### 26 EVALUATION CRITERIA

The CSIR has set minimum standards that a bidder needs to meet in order to be evaluated and selected as a successful bidder. The minimum standards consist of the following:

| Elimination Criteria<br>(Phase 1) | Technical Evaluation Criteria<br>(Phase 2) | Price and Preference Points Evaluation (Phase 3) | Objective Criteria     |
|-----------------------------------|--|--|------------------------|
| Only bidders that comply with     | Bidder(s) are required to achieve          | Bidder(s) will be                                | Bidder(s) may be       |
| ALL the criteria set on           | a predetermined minimum                    | evaluated out of 100                             | evaluated further on   |
| paragraph 27.1 on Phase 1         | threshold on 100 points overall.           | points i.e. 80 or 90                             | Objective Criteria in  |
| below will proceed to             | Only bidder (s) who met and/or             | points for Price and                             | accordance with        |
| Technical/Functional              | exceeded the minimum threshold             | 20 or 10 points for                              | Section (2) (1) (f) of |
| Evaluation (Phase 2).             | points on <b>Phase 2</b> below will        | Preference Points.                               | the PPPFA (Act 5 of    |
|                                   | proceed to Price and Preference            |  | 2000).                 |
|                                   | Points Evaluation.                         |  |                        |
|                                   | (Phase 3)                                  |  |                        |

## 26.1 Elimination Criteria (Phase 1)

Proposals will be eliminated under the following conditions:

- Bidders that submit late bids will not be considered.
- Bidders that submit to the incorrect location or email address will not be considered (Only electronic submission to <a href="tender@csir.co.za">tender@csir.co.za</a> would be considered).
- Bidder that are listed on the NT database of restricted suppliers will not be considered.
- Bidders that are registered on the NT Register of Tender Defaulters will not be considered.
- Bidder that did not submit mandatory returnable documents as Annexure E: Proposal Form and List of Returnable Documents (Mandatory Returnable Documents Table).

## 26.2 Technical Evaluation Criteria (Phase 2)

The evaluation of the functional / technical detail of the proposal will be based on the following criteria:

| No | ELEMENT  | WEIGHT |
|----|--|--------|
| 1  | Proof of the company having successfully assessed and issued /   | 50     |
|    | awarded the CE Mark for medical devices of EU Class IIa (or at a |        |
|    | higher risk level) in the past.                                  |        |

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **15** of **49** 

| 2   | Proof of having current staff members (permanent or contracted to the     | 30  |
|-----|---|-----|
|     | company) with certification scope for medical ultrasound devices of       |     |
|     | EU Class IIa (or higher risk level) who have issued / awarded CE mark     |     |
|     | certification for a EU Class IIa or higher CE Mark in the past five       |     |
|     | years. (To include CV evidence of relevant staff who will work on the     |     |
|     | contract)   |     |
| 3   | Proof of the ability to audit the CE marking processes and award /        | 20  |
|     | issue certification for an EU Class IIa medical device. (Note that a full |     |
|     | technical file according to the South African Health Products             |     |
|     | Regulatory Authority (SAHPRA) requirements has already been               |     |
|     | prepared and electrical and ultrasonic power certifications have been     |     |
|     | certified).   |     |
| TOT | AL (%)  | 100 |

Proposals with functionality / technical points of less than the pre-determined minimum overall percentage of **65%** will be eliminated from further evaluation on Price and Preference Points Evaluation.

Refer to **Annexure C** (**Technical Evaluation Matrix/Rubrics**) for the scoring ranges/rubrics that will be used to evaluate functionality.

## 26.3 Price and Preference Points Evaluation (Phase 3)

Only Bidders that have met meet minimum thresholds on Technical/functional Evaluation will be evaluated for price and preference points. Price and Preference Points will be evaluated as per **Annexure G**: Preference Points Award Form.

#### 27 OBJECTIVE CRITERIA

The CSIR reserves the right to award this tender to a bidder that did not score the highest total number of points in accordance with Section (2) (1) (f) of the PPPFA (Act 5 of 2000)", under the following conditions:

 The directors, shareholders or officers of the bidder must not be formally accused of fraudulent or illegal conduct which could harm the CSIR's reputation by associating with the bidder.

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023

## 28 NATIONAL TREASURY CENTRAL SUPPLIER DATABASE (CSD) REGISTRATION

| Respondents are required to self-register on National Treasury's Central Supplier Database      |
|---|
| (CSD) which has been established to centrally administer supplier information for all organs of |
| state and facilitate the verification of certain key supplier information. Business may not be  |
| awarded to a Respondent who has failed to register on the CSD. Only foreign suppliers with      |
| no local registered entity need not register on the CSD. In order to enable the CSIR to verify  |
| information on the CSD, Respondents are required to provide the unique registration reference   |
| number:   |

Before any negotiations will start with the winning bidder it will be required from the winning bidder to:

- be registered on National Treasury's Central Supplier Database (CSD). Registrations can be completed online at: <a href="https://www.csd.gov.za">www.csd.gov.za</a>;
- provide the CSIR of their CSD registration number.

Request for Proposal

## Annexure A

## Standard Bidding Document (SBD) 1

**PART A: INVITATION TO BID** 

| YOU ARE HERE              | YOU ARE HEREBY INVITED TO BID FOR REQUIREMENTS OF THE CSIR   |                      |   |                           |                                    |         |                     |                 |
|---------------------------|--|----------------------|---|---------------------------|------------------------------------|---------|---------------------|-----------------|
| BID NUMBER:               | RFP<br>1117.   | No<br>1/03/11/2023   | CLOSING DATE:                             |                           | 03 November 2023                   | er CL(  | OSING<br>⁄IE:       | 16H30           |
| DESCRIPTION               |  |                      |   |                           |                                    |         |                     |                 |
|                           | BID RESPONSE DOCUMENTS MAY BE DEPOSITED IN THE BID BOX SITUATED AT (STREET ADDRESS)  In light of the Covid-19 pandemic, the CSIR requires that all tender submissions be submitted electronically to |                      |   |                           |                                    |         |                     |                 |
| In light of the           | Covid-1  | 9 pandemic, the      | CSIR requires t                           | that all ten              | der submissior                     | ns be s | submitted el        | ectronically to |
| tender@csir.co.z          | 2a. Shou   | uld tender file size | e exceed 25MB, bid<br>on of the tender as | lders submit              | t tender in multi<br>on vour email | ple ema | ails. Use the       | tender number   |
|                           |  |                      | Y BE DIRECTED                             | lile subject              | on your email.                     |         |                     |                 |
| то                        |  |                      |   |                           | AL ENQUIRIES                       | MAY     |                     | D TO:           |
| CONTACT PERS              | SON  | Strategic Procur     | ement Unit                                | CONTACT                   | PERSON                             |         | N/A                 |                 |
| TELEPHONE<br>NUMBER       |  | N/A                  |   | TELEPHO                   | NE NUMBER                          |         | N/A                 |                 |
| FACSIMILE NUM             | ИBER   | N/A                  |   | FACSIMIL                  | E NUMBER                           |         | N/A                 |                 |
| E-MAIL ADDRES             |  | tender@csir.co.      | <u>za</u>                                 | E-MAIL AD                 | DDRESS                             |         | tender@             | @csir.co.za     |
| SUPPLIER INFO             | RMAT   | ION                  |   |                           |                                    |         |                     |                 |
| NAME OF BIDD              | ER   |                      |   |                           |                                    |         |                     |                 |
| POSTAL ADDRE              | ESS  |                      |   |                           |                                    |         |                     |                 |
| STREET ADDRE              | ESS  |                      |   |                           |                                    |         |                     |                 |
| TELEPHONE                 |  | CODE                 |   |                           | NUMBER                             |         |                     |                 |
| NUMBER<br>CELLPHONE       |  | CODE                 |   |                           | NUMBER                             |         |                     |                 |
| NUMBER                    |  |                      |   |                           | 1                                  |         |                     |                 |
| FACSIMILE NUM             | MBER   | CODE                 |   |                           | NUMBER                             |         |                     |                 |
| E-MAIL ADDRES             |  |                      |   |                           |                                    |         |                     |                 |
| VAT REGISTRA<br>NUMBER    | ATION  |                      |   |                           |                                    |         |                     |                 |
| SUPPLIER                  |  | TAX<br>COMPLIANCE    |   |                           | CENTRAL<br>SUPPLIER                |         |                     |                 |
| COMPLIANCE STATUS         |  | SYSTEM PIN:          |   | OR                        | DATABASE                           |         |                     |                 |
|                           |  |                      |   |                           | No:                                | MAAA    | ١                   |                 |
| 1 ARE YO THE ACCREDIT     | _  |                      |   |                           | RE YOU A                           |         | □Yes □No            | )               |
| REPRESENTAT               | IVE  |                      | _   | FOREIGN<br>FOR <b>THE</b> | BASED SUPP                         |         |                     |                 |
| IN SOUTH AFRI             |  | □Yes                 | □No                                       |                           | S/WORKS                            |         | [IF YES, AN         |                 |
| FOR THE GOOD /SERVICES/WO |  | [IF YES ENCLO        | SE PROOFI                                 | OFFERED                   | ?                                  |         | QUESTIONN<br>BELOW] | NAIRE           |
| OFFERED?                  | 71110  | [ 120 2.1020         | 021110011                                 |                           |                                    |         | 522011              |                 |
| QUESTIONNAIR              | RE TO E  | BIDDING FOREIG       | SN SUPPLIERS                              |                           |                                    |         |                     |                 |
| IS THE ENTITY             | A RESI   | DENT OF THE R        | EPUBLIC OF SOU                            | TH AFRICA                 | (RSA)?                             |         |                     | ☐ YES           |
| DOES THE ENT              | TTY HA   | VE A BRANCH IN       | N THE RSA?                                |                           |                                    |         |                     | ] YES □ NO      |
| DOES THE ENT              | TTY HA   | VE A PERMANEI        | NT ESTABLISHME                            | NT IN THE                 | RSA?                               |         |                     | YES NO          |
| •                         | OOES THE ENTITY HAVE A PERMANENT ESTABLISHMENT IN THE RSA?   |                      |   |                           |                                    |         |                     |                 |

Request for Proposal CSIR RFP No.: 1117.1/03/11/2023 Page 18 of 49

| DOES THE ENTITY HAVE ANY SOURCE OF INCOME IN THE RSA?   | ☐ YES ☐ NO |
|---|------------|
| IS THE ENTITY LIABLE IN THE RSA FOR ANY FORM OF TAXATION? IF THE ANSWER IS "NO" TO ALL OF THE ABOVE, THEN IT IS NOT A REQUIREMENT TO RE COMPLIANCE STATUS SYSTEM PIN CODE FROM THE SOUTH AFRICAN REVENUE SERVICE REGISTER AS PER 2.3 BELOW. |            |

## PART B: TERMS AND CONDITIONS FOR BIDDING

#### 1. BID SUBMISSION:

- 1.1. BIDS MUST BE DELIVERED BY THE STIPULATED TIME TO THE CORRECT ADDRESS. LATE BIDS WILL NOT BE ACCEPTED FOR CONSIDERATION.
- 1.2. ALL BIDS MUST BE SUBMITTED ON THE OFFICIAL FORMS PROVIDED—(NOT TO BE RE-TYPED) OR IN THE MANNER PRESCRIBED IN THE BID DOCUMENT.
- 1.3. THIS BID IS SUBJECT TO THE PREFERENTIAL PROCUREMENT POLICY FRAMEWORK ACT, 2000 AND THE PREFERENTIAL PROCUREMENT REGULATIONS, 2022, THE GENERAL CONDITIONS OF CONTRACT (GCC) AND, IF APPLICABLE, ANY OTHER SPECIAL CONDITIONS OF CONTRACT.
- 1.4. THE SUCCESSFUL BIDDER WILL BE REQUIRED TO FILL IN AND SIGN A WRITTEN CONTRACT FORM (SBD7).

#### 2. TAX COMPLIANCE REQUIREMENTS

- 2.1 BIDDERS MUST ENSURE COMPLIANCE WITH THEIR TAX OBLIGATIONS.
- 2.2 BIDDERS ARE REQUIRED TO SUBMIT THEIR UNIQUE PERSONAL IDENTIFICATION NUMBER (PIN) ISSUED BY SARS TO ENABLE THE ORGAN OF STATE TO VERIFY THE TAXPAYER'S PROFILE AND TAX STATUS.
- 2.3 APPLICATION FOR TAX COMPLIANCE STATUS (TCS) PIN MAY BE MADE VIA E-FILING THROUGH THE SARS WEBSITE WWW.SARS.GOV.ZA.
- 2.4 BIDDERS MAY ALSO SUBMIT A PRINTED TCS CERTIFICATE TOGETHER WITH THE BID.
- 2.5 IN BIDS WHERE CONSORTIA / JOINT VENTURES / SUB-CONTRACTORS ARE INVOLVED, EACH PARTY MUST SUBMIT A SEPARATE TCS CERTIFICATE / PIN / CSD NUMBER.
- 2.6 WHERE NO TCS PIN IS AVAILABLE BUT THE BIDDER IS REGISTERED ON THE CENTRAL SUPPLIER DATABASE (CSD), A CSD NUMBER MUST BE PROVIDED.
- 2.7 NO BIDS WILL BE CONSIDERED FROM PERSONS IN THE SERVICE OF THE STATE, COMPANIES WITH DIRECTORS WHO ARE PERSONS IN THE SERVICE OF THE STATE, OR CLOSE CORPORATIONS WITH MEMBERS PERSONS IN THE SERVICE OF THE STATE."

# NB: FAILURE TO PROVIDE / OR COMPLY WITH ANY OF THE ABOVE PARTICULARS MAY RENDER THE BID INVALID.

| SIGNATURE OF BIDDER:  |  |
|---|--|
| CAPACITY UNDER WHICH THIS BID IS SIGNED: (Proof of authority must be submitted e.g. company resolution) |  |
| DATE:   |  |

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **19** of **49** 

**Annexure B** 

Technical Specification/Scope of Services for the CE Mark Certification of the

**Umbiflow Medical Device** 

RFP No. 1117.1/03/11/2023

1 INVITATION FOR PROPOSAL

Proposals are hereby invited for the CE Marking of the Umbiflow (continuous-wave foetal

ultrasound) Medical Device, EU Class IIa.

The purpose of the Request for Proposal (RFP) is to obtain capability, pricing and general

information on the business of potential Contractors for the CSIR to determine the Contractors

most capable of providing the service.

This RFP document details and incorporates, as far as possible, the tasks and responsibilities

of the potential bidder required by the CSIR.

This RFP does not constitute an offer to do business with the CSIR, but merely serves as an

invitation to bidder(s) to facilitate a requirements-based decision process.

Responses to this Request for Proposal (RFP) (hereinafter referred to as a Bid or a Proposal)

are requested from suitably qualified entities (hereinafter referred to as a Respondent or

Bidder) for the CE Mark Certification of the Umbiflow (foetal ultrasound) Medical Device.

2 PROPOSAL REQUIREMENTS

All proposals are to be submitted in a format specified in this enquiry However, bidders are

welcome to submit additional / alternative proposals over and above the originally specified

format.

2.1 **Technical Proposal** 

The following must be submitted as part of the **technical** proposal:

a. Company profile.

b. Detailed Technical Proposal

c. Proof of accreditation (authorised representative/body) as a Notified Body able to

assess and issue a CE Mark for the Umbiflow system.

d. Profiles / CVs and experience records of auditors (with specific examples, stating type of devices and risk classes handled) who would handle the case

2.2 Financial Proposal:

The following must be submitted as part of the **financial** proposal:

Cover Letter.

Completed Pricing Schedule (Annexure D) on official company letterhead.

• CSD registration report (RSA suppliers only).

3 PROPOSAL SPECIFICATION

3.1 Scope of Work

The CSIR aims to obtain CE marking for the Umbiflow (EU Class IIa) medical device as soon as possible and the bidder's ability to expedite the CE Marking process is therefore of importance. CE marking is mandatory for Umbiflow's introduction into the South African

market as per regulatory requirements.

Umbiflow has been developed by the CSIR's Industrial Sensors Impact Area within the

Manufacturing Cluster in collaboration with the South African Medical Research Council and

the team holds current certification in ISO 9001 and ISO 13485 along with a SAHPRA

Manufacturing License for Umbiflow for clinical trial application. In compliance with regulatory

requirements, the Cluster aims to obtain CE marking for the Umbiflow medical device (EU

Class IIa). The Umbiflow device has already passed EMC/EMI and ultrasonic radiation

emission tests at accredited labs (in Canada and UK respectively).

NB. All respondents must include proof of Accreditation as a Notified Body with their

quotes.

CSIR RFP No.: 1117.1/03/11/2023 Page **21** of **49** 

## **Annexure C**

## **Technical Evaluation Matrix/Rubrics**

## **CE Mark Certification of the Umbiflow Medical Device**

## RFP No. 1117.1/03/11/2023

Scoring sheet to be used to evaluate functionality

| Criteria  | Score descript  |   |                  |   | Weighting<br>(%) |
|---|---|---|------------------|---|------------------|
| Proof of having issued CE<br>Marks for medical devices of<br>EU Class IIa (or at a higher risk<br>level) in the past  | • Mediun  | the p  ≤ 2 years ago  L  M  H  H  H  (M) = 30 points on (M) = 40 points   | nts out of 50 (8 | years  >5 years & ≤10 years ago L L L H H | 50               |
| Proof of having current staff members (permanent or contracted to the company) with certification scope for medical ultrasound devices of EU Class IIa (or higher risk level) who have successfully audited / issued an EU Class IIa or higher CE Mark in the past five years (to include CV evidence of relevant staff). | on this certific medical ultrase  Staff members their experience and issuing product = 2  Staff members their experimedical ult | their experience does not include the assessment<br>and issuing of CE Marks for a medical ultrasound<br>product = 21 points out of 30 (7) |                  |   |                  |

Request for Proposal CSIR RFP No.: 1117.1/03/11/2023 Page 22 of 49

| Proof of the ability to expedite<br>the assessing / issuing of CE<br>marks for an EU Class IIa<br>medical device | Proof of previous CE Marks of Class Ila or higher in ≤8 months    O devices 1 to 2 devices 3 or more devices  No evidence p Low (L) = 6 po Medium (M) = High (H) = 20 | assess and Umbiflo (on basing file concentrated with the content of the content o | to certify  L  M  H  0 f 20 (3) out of 20 (7) | E Mark for months echnical nostly rocess) | 20  |
|--|---|--|---|---|-----|
| TOTAL  |   |  |   |   | 100 |

Request for Proposal CSIR RFP No.: 1117.1/03/11/2023 Page **23** of **49** 

## **Annexure D**

## **Pricing Schedule - Professional Services**

## **CE Mark Certification of the Umbiflow Medical Device** RFP No. 1117.1/03/11/2023

| ITEM<br>NO. |    | QUANTITY            | DESCRIPT     | TON             | BID PRICE IN<br>** (ALL APPL                           |         |         |     | DED)     |
|-------------|----|---------------------|--------------|-----------------|--|---------|---------|-----|----------|
|             | 1. |                     |              | ition must be i | used for the formu                                     | ılation |         |     |          |
|             |    | of proposa          | ls.          |                 |  |         |         |     |          |
|             | 2. |                     |              |                 | price based on the<br>es and including a<br>applicable |         | for     | the | project. |
|             |    | ·                   |              | or an           | арріюшью   | R       |         |     |          |
|             | 3. | PERSONS<br>RATES AF |              | RTIFIED INVO    | N THE PROJECT<br>DICES MUST BE                         | AND     |         |     |          |
|             | 4. | PERSON A            | AND POSITION |                 |  | HOURLY  | RATE    |     | DAILY    |
|             |    |                     |              |                 |  |         | -R      |     |          |
|             |    |                     | -            |                 |  |         |         |     |          |
|             |    |                     |              |                 |  |         | -R      |     |          |
|             |    |                     | -            |                 |  |         |         |     |          |
|             |    |                     | -            |                 |  |         |         |     |          |
|             |    |                     |              |                 |  |         | -R      |     |          |
|             |    |                     | -            |                 |  |         |         |     |          |
|             |    |                     | _            |                 |  |         | - K<br> |     |          |
|             | 5. |                     |              |                 | /HICH THE PROJ<br>HASE AND MAN-                        |         |         |     |          |
|             |    |                     |              |                 |  |         | R       |     |          |
|             |    |                     |              |                 |  | da      | ys      |     |          |

Request for Proposal CSIR RFP No.: 1117.1/03/11/2023 Page 24 of 49

|         |             |  | days                                  |               |
|---------|-------------|--|---------------------------------------|---------------|
|         |             |  | days                                  |               |
|         |             |  | R-<br>days                            |               |
|         | 5.1         | Travel expenses (specify, for example rate/kn of airtravel, etc). Only actual costs are recove expenses incurred must accompany certified  | erable. Proof of t                    |               |
|         | DESCRI      | PTION OF EXPENSE TO BE INCURRED  | RATE<br>AMOUNT                        | QUANTITY      |
|         |             |  |                                       | R             |
|         |             |  |                                       | R             |
|         |             |  |                                       | R             |
|         |             |  |                                       | <br>R         |
|         |             | TC   | TAL:                                  |               |
|         |             | R  |                                       |               |
| "all ap | plicable ta | axes" includes value- added tax, pay as you ea<br>insurance fund contributions and skills develo   |                                       | unemployment  |
|         | 5.2         | Other expenses, for example accommodation star hotel, bed and breakfast, telephone cost, etc.). On basis of these particulars, certified i for correctness. Proof of the expenses must a | reproduction cos<br>nvoices will be c | st,<br>hecked |
|         |             | DESCRIPTION OF EXPENSE TO BE INCUR<br>QUANTITY AMOUNT  | RED                                   | RATE          |
|         |             | R  |                                       |               |
|         |             |  |                                       |               |
|         |             | R  |                                       |               |
|         |             | D  |                                       |               |
|         |             | R  |                                       |               |
|         |             | D  | <b></b>                               |               |

|    | R                                     |                       | 101        | AL:                  |       |
|----|---------------------------------------|-----------------------|------------|----------------------|-------|
| 6. | Period required for acceptance of bid |                       |            | r<br>                |       |
| 7. | Estimated project                     | ,                     |            | completion           | of    |
| 8. | Are the rates quote                   | d firm for the full p |            | ct?<br>S/NO          |       |
| 9. | index                                 | be applied            | for, for o | example consumer<br> | price |
|    |                                       |                       |            |                      |       |

## Annexure E

## **Proposal Form and List of Returnable Documents**

# CE Mark Certification of the Umbiflow Medical Device RFP No. 1117.1/03/11/2023

| I/We  |                                      |   |               |   |  |                 |  |                 |         |                         |
|---|--------------------------------------|---|---------------|---|--|-----------------|--|-----------------|---------|-------------------------|
| [name                                       | of                                   | entity,                                   | company,      | close                                     | corporation                                  | or              | partnership]   | of              | [full   | address                 |
| carryin                                     | g on l                               | ousiness                                  | trading/opera | ating as                                  |  |                 |  |                 |         |                         |
| represe                                     | ented                                | by  |               |   |  |                 |  | i               | n my c  | apacity as              |
| of Parti<br>relating<br>authoris<br>Post Te | ners,<br>I to the<br>sed to<br>ender | dated<br>nis propos<br>negotia<br>Negotia | sal and any s | to<br>ubseque<br>of the al<br>ortlisted l | enter into, sigent Agreement<br>bovementione | gn ex<br>t. The | f Directors or Nacecute and consecute and co | nplete<br>of pe | e any o | documents<br>are hereby |

I/We hereby offer to supply the abovementioned Services at the prices quoted in the schedule of prices in accordance with the terms set forth in the documents listed in the accompanying schedule of RFP documents.

I/We agree to be bound by those conditions in CSIR's:

1. General RFP Terms and Conditions; and CSIR's Purchasing Terms and Conditions or

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **27** of **49** 

Any other standard or special conditions mentioned and/or embodied in this Request for Proposal.

I/We accept that unless CSIR should otherwise decide and so inform me/us in the letter of award/intent, this Proposal [and, if any, its covering letter and any subsequent exchange of correspondence], together with CSIR's acceptance thereof shall constitute a binding contract between CSIR and me/us.

I/We further agree that if, after I/we have been notified of the acceptance of my/our Proposal, I/we fail to enter into a formal contract if called upon to do so, or fail to commence the supply of Services within 4 [four] weeks thereafter, CSIR may, without prejudice to any other legal remedy which it may have, recover from me/us any expense to which it may have been put in calling for Proposals afresh and/or having to accept any less favourable Proposal.

I/We accept that any contract resulting from this offer will be for a period as determined by the CSIR.

Furthermore, I/we agree to a penalty clause/s which will allow CSIR to invoke a penalty against us for non-compliance with material terms of this RFP including the delayed delivery of the Services due to non-performance by ourselves, failure to meet Subcontracting.

I/we agree that non-compliance with any of the material terms of this RFP, including those mentioned above, will constitute a material breach of contract and provide CSIR with cause for cancellation.

#### **ADDRESS FOR NOTICES**

The law of the Republic of South Africa shall govern any contract created by the acceptance of this RFP. The domicilium citandi et executandi shall be a place in the Republic of South Africa to be specified by the Respondent hereunder, at which all legal documents may be served on the Respondent who shall agree to submit to the jurisdiction of the courts of the Republic of South Africa. Foreign Respondents shall, therefore, state hereunder the name of their authorised representative in the Republic of South Africa who has the power of attorney to sign any contract which may have to be entered into in the event of their Proposal being accepted and to act on their behalf in all matters relating to such contract.

| Respondent to indicate the details of its domicilium citandi et executandi hereunder:<br>Name of Entity: |  |  |  |  |  |
|--|--|--|--|--|--|
| Facsimile:   |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

CSIR RFP No.: 1117.1/03/11/2023 Page **28** of **49** 

### NOTIFICATION OF AWARD OF RFP

As soon as possible after approval to award the contract(s), the successful Respondent [the Service provider] will be informed of the acceptance of its Proposal. Unsuccessful Respondents may be advised in writing of the name of the successful Service provider and the reason as to why their Proposals have been unsuccessful, for example, in the category of price, delivery period, quality, B-BBEE or for any other reason.

#### **VALIDITY PERIOD**

CSIR requires a validity period of 90 [Ninety calendar Days from closing date] against this RFP.

Bidders are to note that they may be requested to extend the validity period of their bid, at the same terms and conditions, if the internal evaluation process has not been finalised within the validity period. However, once the adjudication body has approved the process and award of the business to the successful bidder(s), the validity of the successful bidder(s)' bid will be deemed to remain valid until a final contract has been concluded.

## NAME(S) AND ADDRESS / ADDRESSES OF DIRECTOR(S) OR MEMBER(S)

The Respondent must disclose hereunder the full name(s) and address(s) of the director(s) or members of the company or close corporation [C.C.] on whose behalf the RFP is submitted.

| 1. | Registration number of company / C.C.                             |
|----|---|
| 2. | Registered name of company / C.C.                                 |
| 3. | Full name(s) of director/member(s) Address/Addresses ID Number(s) |
|    |   |
|    |   |

#### **RETURNABLE DOCUMENTS**

All Sections, as indicated in the footer of each page, must be signed, stamped and dated by the Respondent. **Returnable Documents** means all the documents, Sections and Annexures, as listed in the tables below.

## a) Mandatory Returnable Documents

Failure to provide any Mandatory Returnable Documents at the closing date and time of this bid <u>will</u> result in a Respondent's disqualification. Bidders are therefore urged to ensure that all these documents are returned with their Proposals.

Please confirm submission of the mandatory Returnable Documents detailed below by so indicating [Yes or No] in the table below:

| MANDATORY RETURNABLE DOCUMENTS  | SUBMITTED [Yes/No] |
|---|--------------------|
| Completed Pricing Schedule on official company letterhead   |                    |
| All respondents must include proof of registration as an Accreditation / Certification Body with their quotes                                     |                    |
| In the case of Joint Ventures, bidder must submit a copy of the <u>signed</u> Joint Venture Agreement.  |                    |
| In the case of subcontracting arrangements, bidder must submit a copy of the <b>signed</b> subcontracting agreement.                              |                    |
| Bidders who cannot provide proof of having assessed and issued a CE Mark in   |                    |
| the past five years for a medical device at an EU Class 2a (or higher risk level) will be eliminated.   |                    |
| Bidders who do not provide any CVs in their submission of persons with certification scope for medical ultrasound devices will not be considered. |                    |

#### b) Essential Returnable Documents

In addition to the requirements of section (a) above, Respondents are further required to submit with their Proposals the following **essential Returnable Documents** as detailed below.

Essential Returnable Documents required for evaluation purposes:

Failure to provide any essential Returnable Documents used for purposes of scoring a bid, by the closing date and time of this bid will not result in a Respondent's disqualification. However, Bidders will receive an automatic score of zero for the applicable evaluation criterion. Bidders are therefore urged to ensure that all these documents are returned with their Proposals.

Please confirm submission of these essential Returnable Documents by so indicating [Yes or No] in the table below:

## **ESSENTIAL RETURNABLE DOCUMENTS USED FOR SCORING**

SUBMITTED

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **30** of **49** 

| Annexure A: Standard Bidding Document (SBD) 1 Form   |   |  |  |  |  |
|--|---|--|--|--|--|
| Annexure I: Standard Bidding Document (SBD) 4 Form   |   |  |  |  |  |
| Annexure G: Preference Points Award Form in Terms of the Preferential Procurement Regulations 2022 (Mandatory documents to claim preference points)  |   |  |  |  |  |
| Valid copy of BBBEE certificate/ sworn affidavit   |   |  |  |  |  |
| ✓ In case of unincorporated trust, consortium or joint venture, they<br>must submit their consolidated B-BBEE scorecard with their<br>individual B-BBEE Certificate or Sworn Affidavit.  |   |  |  |  |  |
| ✓ In case of sub-contracting both parties must submit copies of their valid BBBEE certificates.  |   |  |  |  |  |
| NB: Non-submission or invalid submission will result in zero points. Should the individual entity's B-BBEE Certificate or Sworn Affidavit of the unincorporated trust, consortium or joint venture parties <b>be invalid</b> , the joint venture scorecard will also be invalid. | NB: Non-submission or invalid submission will result in zero points. Should the individual entity's B-BBEE Certificate or Sworn Affidavit of the unincorporated trust, consortium or joint venture parties <b>be invalid</b> , the joint venture scorecard will |  |  |  |  |

## **Other Essential Returnable Documents:**

Failure to provide other essential Returnable Documents  $\underline{may}$  result in a Respondent's disqualification. Bidders are therefore urged to ensure that all these documents are returned with their Proposals.

Please confirm submission of these essential Returnable Documents by indicating Yes or No in the table below

| OTHER ESSENTIAL RETURNABLE DOCUMENTS                                       | SUBMITTED |
|--|-----------|
|  | [Yes/No]  |
| Annexure E: Proposal Form and List of Returnable documents (This document) |           |
| Annexure F: Certificate of Acquaintance with RFP, Terms & Conditions &     |           |
| Applicable Documents   |           |
| Annexure J: RFP Declaration and Breach of Law Form                         |           |
| Annexure K: Mutual Non-Disclosure Agreement                                |           |

Request for Proposal CSIR RFP No.: 1117.1/03/11/2023 Page 31 of 49

## CONTINUED VALIDITY OF RETURNABLE DOCUMENTS

The successful Respondent will be required to ensure the validity of all returnable documents, including but not limited to its Tax Clearance Certificate and valid B-BBEE Verification Certificate, for the duration of any contract emanating from this RFP. Should the Respondent be awarded the contract [the Agreement] and fail to present CSIR with such renewals as and when they become due, CSIR shall be entitled, in addition to any other rights and remedies that it may have in terms of the eventual Agreement, to terminate such Agreement forthwith without any liability and without prejudice to any claims which CSIR may have for damages against the Respondent.

| SIGNED at                  | on this | day of | 20 |
|----------------------------|---------|--------|----|
| SIGNATURE OF WITNESSES ADD |         |        |    |
| Name                       |         |        |    |
| 2                          |         |        |    |
| Name                       |         |        | _  |
| SIGNATURE OF RESPONDENT'S  |         |        |    |
| Name:                      |         |        |    |
| Designation:               |         |        |    |

## **Annexure F**

## Certificate of Acquaintance with RFP, Terms & Conditions & Applicable Documents

## **CE Mark Certification of the Umbiflow Medical Device**

RFP No. 1117.1/03/11/2023

By signing this certificate the Respondent is deemed to acknowledge that he/she has made himself/herself thoroughly familiar with, and agrees with all the conditions governing this RFP. This includes those terms and conditions contained in any printed form stated to form part hereof, including but not limited to the documents stated below. As such, CSIR will recognise no claim for relief based on an allegation that the Respondent overlooked any such condition or failed properly to take it into account for the purpose of calculating tendered prices or any other purpose:

Should the Bidder find any terms or conditions stipulated in any of the relevant documents quoted in the RFP unacceptable, it should indicate which conditions are unacceptable and offer alternatives by written submission on its company letterhead, attached to its submitted Bid. Any such submission shall be subject to review by CSIR's Legal Counsel who shall determine whether the proposed alternative(s) are acceptable or otherwise, as the case may be. A material deviation from any term or condition may result in disqualification.

Bidders accept that an obligation rests on them to clarify any uncertainties regarding any bid which they intend to respond on, before submitting the bid. The Bidder agrees that he/she will have no claim based on an allegation that any aspect of this RFP was unclear but in respect of which he/she failed to obtain clarity.

The bidder understands that his/her Bid will be disqualified if the Certificate of Acquaintance with RFP documents included in the RFP as a returnable document, is found not to be true and complete in every respect.

| SIGNED at            | on this             | day of          | 20 |
|----------------------|---------------------|-----------------|----|
|                      |                     |                 |    |
| SIGNATURE OF WITNESS | SES ADDRESS OF WITH | NESSES          |    |
| 1                    |                     |                 |    |
| Name                 |                     |                 |    |
| 2                    |                     |                 |    |
| Name                 |                     |                 |    |
|                      |                     |                 |    |
| SIGNATURE OF RESPON  | DENT'S AUTHORISED   | REPRESENTATIVE: |    |
|                      |                     |                 |    |
| Name:                |                     |                 |    |
| Designation:         |                     |                 |    |
| D (( D )             |                     |                 |    |

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **33** of **49** 

#### **Annexure G**

# Preference Points Award Form in Terms of the Preferential Procurement Regulations 2022

## CE Mark Certification of the Umbiflow Medical Device RFP No. 1117.1/03/11/2023

This preference form must form part of all bids invited. It contains general information and serves as a claim form for the preference points allocated on the basis of specific goals outlined in point 3 below.

NB: BEFORE COMPLETING THIS FORM, BIDDERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF SPECIFIC GOALS, AS PRESCRIBED IN THE PREFERENTIAL PROCUREMENT REGULATIONS, 2022

#### 1. GENERAL CONDITIONS

- 1.1 The following preference point systems are applicable to this bid:
  - the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included). The lowest acceptable tender will be used to determine the applicable preference point system.
- 1.2 Points for this bid shall be awarded for:
  - (a) Price; and
  - (b) Preference Points based on specific goals.
- 1.3 The maximum points for this bid are allocated as follows:

|   | POINTS |
|---|--------|
| PRICE   | 80     |
| Preference Points   | 20     |
| Total points for Price and Preference Points mus not exceed | 100    |

- 1.4 Failure on the part of a bidder to submit proof of preference points together with the bid, will be interpreted to mean that preference points are not claimed.
- 1.5 The CSIR reserves the right to require of a bidder, either before a bid is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the CSIR.

#### 2. POINTS AWARDED FOR PRICE

#### 2.1 THE 80/20 PREFERENCE POINT SYSTEMS

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **34** of **49** 

A maximum of 80 points is allocated for price on the following basis:

## 80/20

$$Ps = 80 \left( 1 - \frac{Pt - P\min}{P\min} \right)$$

Where

Ps = Points scored for price of bid under consideration

Pt = Price of bid under consideration

Pmin = Price of lowest acceptable bid

## 3. PREFERENCE POINTS AWARDED

3.1 In terms of Regulation 4 (2) and 4 (2) of the Preferential Procurement Regulations, preference points may be awarded to a bidder for the specific goal specified for the tender in accordance with the table below:

3.2 Specific goals must be determined per tender.

| Specific Goals  | Preference Points |
|-----------------|-------------------|
| Black Ownership | 20                |
| Total           | 20                |

- 3.3 Total preference points per specific goal to be determined per tender.
- 3.3.1. Total preference points per specific goal to be awarded as follows:
- 3.3.1.1. Preferential points for black ownership will be awarded as follows:

| Black Ownership                           | % of Preferential points |
|---|--------------------------|
| Bidder with 100% black ownership          | 100%                     |
| Bidder with 51% to 99% black ownership    | 50%                      |
| Bidder with less than 51% black ownership | 0%                       |

## 3.4. Joint Ventures, Consortiums and Trusts

A trust, consortium or joint venture<sup>1,</sup> will qualify for preference points as a legal entity (Incorporated), provided that the entity submits its valid B-BBEE certificate. Only valid BBBEE

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **35** of **49** 

<sup>&</sup>lt;sup>1</sup> Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

certificates issued by SANAS accredited verification agency will be considered for allocation of points.

A trust, consortium or joint venture will qualify for preference points as an unincorporated entity, provided that the entity submits their consolidated B-BBEE scorecard as if they were a group structure and that such a consolidated B-BBEE scorecard is prepared for every separate bid. Only valid consolidated BBBEE certificates issued by SANAS accredited verification agency will be considered for allocation of points.

Bidders must submit concrete proof of the existence of joint ventures and/or consortium arrangements. The CSIR will accept signed agreements as acceptable proof of the existence of a joint venture and/or consortium arrangement. Furthermore, in bids where unincorporated joint venture and/or consortium/sub-contractors are involved, each party must submit a separate TCS PIN and CSD number.

The joint venture and/or consortium agreements must clearly set out the roles and responsibilities of the Lead Partner and the joint venture and/or consortium party. The agreement must also clearly identify the Lead Partner, who shall be given the power of attorney to bind the other party/parties in respect of matters pertaining to the joint venture and/or consortium arrangement.

## 3.5. Sub-contracting

A bidder must not be awarded preference points if it is indicated in the tender documents that such a bidder intends sub- contracting more than 25% of the value of the contract to any other enterprise that does not qualify for at least the points that such a bidder qualifies for, unless the intended sub-contractor is an EME that has the capability and ability to execute the sub-contract.

A bidder awarded a contract may not sub-contract more than 25% of the value of the contract to any other enterprise that does not have an equal or higher B-BBEE status level than the bidder concerned, unless the contract is sub-contracted to an EME that has the capability and ability to execute the sub-contract.

#### 4. BID DECLARATION

4.3. Bidders who claim points in respect of specific goals **must** submit the following documents:

|   |     | Submitted |  |
|---|-----|-----------|--|
| Mandatory documents to claim preference points                            | Yes | No        |  |
|   |     | $\sqrt{}$ |  |
| Valid copy of BBBEE certificate/ sworn affidavit to claim Black Ownership |     |           |  |

#### DECLARATION WITH REGARD TO COMPANY/FIRM

| Name of company/firm:        |
|------------------------------|
| VAT registration number:     |
| Company registration number: |

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **36** of **49** 

I/we, the undersigned, who is / are duly authorised to do so on behalf of the company/firm, certify that the documents submitted to claim preference points based on the specific goals are valid, and I / we acknowledge that:

- i) The information furnished is true and correct;
- ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 3 of this form;
- iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 3, the contractor may be required to furnish further documentary proof to the satisfaction of the CSIR that the awarded are correct:
- iv) If any document is obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the CSIR may, in addition to any other remedy it may have
  - (a) disgualify the person from the bidding process;
  - (b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;
  - (c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;
- (d) recommend that the bidder or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted by the National Treasury from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and
- (e) forward the matter for criminal prosecution.
  - v) If the CSIR is of the view that a bidder submitted false information regarding a specific goal, it must—
    - (a) inform the bidder accordingly; and
    - (b) give the bidder an opportunity to make representations within 14 days as to why the tender may not be disqualified or, if the tender has already been awarded to the bidder, the contract should not be terminated in whole or in part.
  - vi) After considering the representations referred to in subregulation (v)(b), the CSIR may, if it concludes that such information is false—
    - (a) disqualify the bidder or terminate the contract in whole or in part; and
    - (b) if applicable, claim damages from the bidder.

| WITNESSES |                            |
|-----------|----------------------------|
| 1         | SIGNATURE(S) OF BIDDERS(S) |
| 2         | DATE:                      |
|           | ADDRESS                    |

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **37** of **49** 

## **Annexure H**

## **RFP Clarification Request Form**

# CE Mark Certification of the Umbiflow (continuous-wave foetal ultrasound) Medical Device, EU Class IIa to the CSIR

## RFP No. 1117.1/03/11/2023

| RFP deadline for questions / RFP Clarifications: Before 16h30 on 20 October 2023 |  |  |  |
|--|--|--|--|
| TO: CSIR   |  |  |  |
| ATTENTION: Strategic Procurement Unit  |  |  |  |
| EMAIL tender@csir.co.za  |  |  |  |
| DATE:  |  |  |  |
| FROM:  |  |  |  |
|  |  |  |  |
| RFP Clarification No   |  |  |  |
| RFP No 1117.1/03/11/2023   |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Annexure I Standard Bidding Document (SBD) 4

#### **BIDDER'S DISCLOSURE**

#### 1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

| <b>2. Bi</b><br>2.1<br>2.1.1 | person having a controlli<br>employed by the state?<br>If so, furnish particulars<br>employee numbers of | ts directors / trustees / shaing interest <sup>2</sup> in the enterprior of the names, individual id sole proprietor/ directors having a controlling interes | yes // // // // // // // // // // // // // | , if applicable, state |
|------------------------------|--|--|--|------------------------|
|                              | Full Name  | Identity Number  | Name of institution                        | State                  |
|                              |  |  | manun                                      |                        |
|                              |  |  |  |                        |
|                              |  |  |  |                        |
|                              |  |  |  |                        |
|                              |  |  |  |                        |
|                              |  |  |  |                        |
| 2.2                          | Do you, or any person co   | onnected with the bidder, huring institution?  | nave a relationship v                      | vith any person who    |
| 2.2.1                        | If so, furnish particulars   | :  |  |                        |
| 2 the po                     | ower, by one person or a gro   | oup of persons holding the ma  | aiority of the equity of                   | an enterprise.         |

Request for Proposal

decisions of the enterprise.

CSIR RFP No.: 1117.1/03/11/2023 Page **39** of **49** 

alternatively, the person/s having the deciding vote or power to influence or to direct the course and

| 2.3   | Does the bidder or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterprise have any interest in any other related enterprise whether or not they are bidding for this contract? YES /NO /NO |
|-------|---|
| 2.3.1 | If so, furnish particulars:   |
|       |   |

#### 3 DECLARATION

I, the undersigned, (name)......in submitting the accompanying bid, do hereby make the following statements that I certify to be true and complete in every respect:

- 3.1 I have read and I understand the contents of this disclosure;
- 3.2 I understand that the accompanying bid will be disqualified if this disclosure is found not to be true and complete in every respect;
- 3.3 The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement or arrangement with any competitor. However, communication between partners in a joint venture or consortium<sup>3</sup> will not be construed as collusive bidding.
- 3.4 In addition, there have been no consultations, communications, agreements or arrangements with any competitor regarding the quality, quantity, specifications, prices, including methods, factors or formulas used to calculate prices, market allocation, the intention or decision to submit or not to submit the bid, bidding with the intention not to win the bid and conditions or delivery particulars of the products or services to which this bid invitation relates.
- 3.4 The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.
- 3.5 There have been no consultations, communications, agreements or arrangements made by the bidder with any official of the procuring institution in relation to this procurement process prior to and during the bidding process except to provide clarification on the bid submitted where so required by the institution; and the bidder was not involved in the drafting of the specifications or terms of reference for this bid.
- 3.6 I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **40** of **49** 

<sup>&</sup>lt;sup>3</sup> Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

No 12 of 2004 or any other applicable legislation.

I CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 1, 2 and 3 ABOVE IS CORRECT.

I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH 6 OF PFMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

| Signature | Date           |
|-----------|----------------|
| Position  | Name of bidder |

#### Annexure J

### DECLARATION BY BIDDER AND BREACH OF LAW FORM

## CE Mark Certification of the Umbiflow Medical Device RFP No. 1117.1/03/11/2023

Only bidders who completed the declaration below will be considered for evaluation.

| NAME OF ENTITY: |    |        |         |
|-----------------|----|--------|---------|
| We              | do | hereby | certify |
| that:           |    | -      | -       |

- 1. CSIR has supplied and we have received appropriate responses to any/all questions [as applicable] which were submitted by ourselves for RFP Clarification purposes;
- 2. we have received all information we deemed necessary for the completion of this Request for Proposal [RFP];
- 3. we have been provided with sufficient access to the existing CSIR facilities/sites and any and all relevant information relevant to the Services as well as CSIR information and Employees, and has had sufficient time in which to conduct and perform a thorough due diligence of CSIR's operations and business requirements and assets used by CSIR. CSIR will therefore not consider or permit any pre- or post-contract verification or any related adjustment to pricing, service levels or any other provisions/conditions based on any incorrect assumptions made by the Respondent in arriving at his Bid Price.
- 4. at no stage have we received additional information relating to the subject matter of this RFP from CSIR sources, other than information formally received from the designated CSIR contact(s) as nominated in the RFP documents:
- 5. we are satisfied, insofar as our entity is concerned, that the processes and procedures adopted by CSIR in issuing this RFP and the requirements requested from Bidders in responding to this RFP have been conducted in a fair and transparent manner; and
- 6. we have complied with all Obligations of the Bidder/Supplier as indicated in paragraph 3 of the CSIR Supplier Integrity which includes but is not limited to ensuring that we take all measures necessary to prevent corrupt practices, unfairness and illegal activities in order to secure or in furtherance to secure a contract with CSIR;
- 7. furthermore, we declare that a family, business and/or social relationship exists / does not exist [delete as applicable] between an owner / member / director / partner / shareholder of our entity and an employee or board member of the CSIR Group including any person who may be involved in the evaluation and/or adjudication of this Bid.
- 8. In addition, we declare that an owner / member / director / partner / shareholder of our entity is / is not [delete as applicable] an employee or board member of the CSIR.
- 9. If such a relationship as indicated in paragraph 6 and/or 7 exists, the Respondent is to complete the following section:

Request for Proposal

CSIR RFP No.: 1117.1/03/11/2023 Page **42** of **49** 

|                | FULL NAME OF OWNER/MEMBER/DIRECTOR/ PARTNER/SHAREHOLDER: ADDRESS:  |  |  |  |
|----------------|--|--|--|--|
| Indic          | cate nature of relationship with CSIR:   |  |  |  |
| disq           | ure to furnish complete and accurate information in this regard will lead to the pualification of a response and may preclude a Respondent from doing future business CSIR1  |  |  |  |
| 10.            | We declare, to the extent that we are aware or become aware of any relationship between ourselves and CSIR [other than any existing and appropriate business relationship with CSIR] which could unfairly advantage our entity in the forthcoming adjudication process, we shall notify CSIR immediately in writing of such circumstances.   |  |  |  |
| 11.            | We accept that any dispute pertaining to this Bid will be resolved through the Ombudsman process and will be subject to the Terms of Reference of the Ombudsman. The Ombudsman process must first be exhausted before judicial review of a decision is sought.   |  |  |  |
| 12.            | We further accept that CSIR reserves the right to reverse an award of business or decision based on the recommendations of the Ombudsman without having to follow a formal court process to have such award or decision set aside.   |  |  |  |
| <b>BRE</b> 13. | EACH OF LAW  We further hereby certify that I/we (the bidding entity and/or any of its directors, members or   |  |  |  |
| 10.            | partners) have/have not been [delete as applicable] found guilty during the preceding 5 [five] years of a serious breach of law, including but not limited to a breach of the Competition Act, 89 of 1998, by a court of law, tribunal or other administrative body. The type of breach that the Respondent is required to disclose excludes relatively minor offences or misdemeanours, e.g. traffic offences. This includes the imposition of an administrative fine or penalty. |  |  |  |
|                | ere found guilty of such a serious breach, please disclose:<br>TURE OF BREACH:   |  |  |  |
|                |  |  |  |  |
|                |  |  |  |  |
| Furtl<br>bidd  | E OF BREACH:   |  |  |  |

Request for Proposal CSIR RFP No.: 1117.1/03/11/2023 Page **43** of **49** 

| SIGNED at              | on this day of | 20                |
|------------------------|----------------|-------------------|
| For and on behalf of   | AS WITNESS:    |                   |
| duly authorised hereto |                |                   |
| Name:                  | Name:          |                   |
| Position:              | Position:      |                   |
| Signature:             | Signature:     |                   |
| Date                   | Registration N | o of Company/CC   |
| Place                  | Registration N | ame of Company/CC |

# Annexure K Mutual Non-Disclosure Agreement

#### **MUTUAL NON-DISCLOSURE AGREEMENT**

#### 1 Preamble

The Parties as identified herein are engaged in discussions relating to their potential collaboration in the Field as likewise described therein; are by virtue thereof are required to disclose Confidential Information to one another, and have agreed to do so subject to the terms and conditions as set out in this agreement.

#### 2 Definitions

- 2.1 The following words and/or phrases, when used in this agreement, shall have the following meanings:
- 2.1.1 "Confidential Information" shall mean all scientific, technical, business, financial, past, present or future research, development, business activities, products, services and technical knowledge or marketing information, whether inside or outside the Field, which one party (the "Disclosing Party") discloses to the other party (the "Receiving Party") in connection with the discussions, and either has been identified in writing as confidential or is of such a nature (or has been disclosed in such a way) that it should be obvious to the Receiving Party that it constitutes Confidential Information. (Without limiting the generality of the aforegoing, "Confidential Information" shall include any information that falls within the definition of 'Personal Information'
- 2.1.2 "Disclosing Party" shall mean the Party disclosing Confidential Information under this agreement;
- 2.1.3 "Disclosing Purpose" shall mean, as pertains to any particular joint opportunity(ies) in the Field, the discussions held or to be held between the Parties regarding their possible collaboration and future working relationship with regards to any such opportunity(ies);
- 2.1.4 "Effective Date' shall mean the date of the commencement of this agreement herein";
- 2.1.5 "Notice" shall mean a written document addressed by one Party to the other and either delivered by hand; sent per registered post or telefaxed to the addresses as indicated herein";
- 2.1.6 "Personal Information" means any information that falls within the definition of 'Personal Information' as defined in the Protection of Personal Information Act, No 4 of 2013 ("POPI");
- 2.1.7 "Receiving Party" shall mean the Party receiving Confidential Information under this agreement;

"Responsible Party" means a public or private body or any other person which, alone or in conjunction with others, determines the purpose of and means for processing personal information, as defined in POPI.

## 3 Obligation of Confidentiality

- 3.1 The Receiving Party undertakes and agrees:
- 3.1.1 to use the Disclosing Party's Confidential Information only to give effect to the Disclosing Purpose;
- 3.1.2to hold in strict confidence and not to publish or disclose to any unauthorised third parties any of the Confidential Information of the Disclosing Party without the prior written consent of the Disclosing Party;
- 3.1.3 to use the same degree of care (and in any event not less than reasonable care) to safeguard the confidentiality of the Disclosing Party's Confidential Information that it uses to protect its own information of like kind;
- 3.1.4to limit any disclosure of such Confidential Information only to those of its employees and professional advisors who have a specific need to- know to access such Confidential Information and either entered into a written agreement which impose, or are otherwise bound by the same restrictions as those imposed upon it by virtue of this agreement;
- 3.1.5 not to disclose or reveal to any third party, whomsoever, either the fact that discussions or negotiations are taking, or have taken, place between the Parties; the content of any such discussions, or other facts relating to the Disclosing Purpose;
- 3.1.6 on termination of this agreement, to act with the Disclosing Party's Confidential Information in accordance with a Notice delivered to it by the Disclosing Party, and if no such Notice is delivered to the Recipient, to destroy the Disclosing Party's Confidential Information in a similar manner to which it would destroy its own Confidential Information.

#### 4 Protection of Personal Information

- 4.1 The Party(ies) undertake(s) to:-
- 4.1.1 comply with the provisions of POPI as well as all applicable legislation as amended or substituted from time to time;
- 4.1.2 treat all Personal Information strictly as defined within the parameters of POPI;
- 4.1.3 process Personal Information only in accordance with the consent it was obtained for, for the purpose agreed, any lawful and reasonable written instructions received from the applicable Responsible Party and as permitted by law;
- 4.1.4 process Personal Information in compliance with the requirements of all applicable laws;
- 4.1.5 secure the integrity and confidentiality of any Personal Information in its possession or under its control by taking appropriate, reasonable technical and organisational measures to prevent loss, damage, unauthorised destruction, access,

- use, disclosure or any other unlawful processing of Personal Information:
- 4.1.6 not transfer any Personal Information to any third party in a foreign country unless such transfer complies with the relevant provisions of POPI regarding transborder information flows; and
- 4.1.7 not retain any Personal Information for longer than is necessary for achieving the purpose in terms of this Agreement or in fulfilment of any other lawful requirement.
- 4.2 The Party(ies) undertake(s) to ensure that all reasonable measures are taken to:
- 4.2.1 identify reasonably foreseeable internal and external risks to the Personal Information in its possession or under its control;
- 4.2.2 establish and maintain appropriate security safeguards against the identified risks;
- 4.2.3 regularly verify that the security safeguards are effectively implemented;
- 4.2.4 ensure that the security safeguards are continually updated in response to new risks or deficiencies in previously implemented safeguards;
- 4.2.5 provide immediate notification to the Responsible Party if a breach in information security or any other applicable security safeguard occurs; provide immediate notification to the Responsible Party where there are reasonable grounds to believe that the Personal Information has been accessed or acquired by any unauthorised person:
- 4.2.6 remedy any breach of a security safeguard in the shortest reasonable time and provide the Responsible Party with the details of the breach and, if applicable, the reasonable measures implemented to address the security safeguard breach;
- 4.2.7 provide immediate notification to the Responsible Party where either party has, or reasonably suspects that, Personal Information has been processed outside of the purpose agreed to or consented to;
- 4.2.8 provide the Responsible Party, upon request, with all information of any nature whatsoever relating to the processing of the Personal Information for the purpose in terms of this Agreement and any applicable law; and
- 4.2.9 notify the CSIR, if lawful, of receipt of any request for access to Personal Information, in its possession and relating to the CSIR.
- 4.3 The CSIR reserves the right to inspect the Personal Information processing operations, as well as the technical and organisational information security measures employed by the contracting Party to ensure compliance with the provisions of clause 4.
- 4.4 The provisions of clause 4 shall survive the termination of this Agreement, regardless of cause, in perpetuity.

#### 5 Exclusions

- 5.1 The Receiving Party recognises that this agreement is not intended to restrict use or disclosure of any portion of the Disclosing Party's Confidential Information which:
- 5.1.1 is as at the Effective Date, or later, made known to the public or otherwise enters the public domain through no default by the Receiving Party of its obligations under this Agreement;
- 5.1.2it can show was in its possession prior to the earliest disclosure by the Disclosing Party, as evidenced by written documents in its files;
- 5.1.3 is rightfully received by it from a third party having no obligation of confidentiality to the Disclosing Party;
- 5.1.4 is independently developed by the Receiving Party by a person(s) who did not have access to the Confidential Information of the Disclosing Party:
- 5.1.5 is disclosed by the Receiving Party after receipt of written permission from the Disclosing Party; or
- 5.1.6it is requested or required by subpoena, court order, or similar process to disclose, provided that, in such an event, it will provide the Disclosing Party with prompt written notice of such request(s) so that the latter may seek an appropriate protective order and/or waive the Receiving Party's compliance with the provisions of this agreement.

#### 6 Ownership and Provision of Information

- 6.1 The Disclosing Party shall retain ownership of all its Confidential Information as disclosed hereunder.
- 6.2 Nothing contained in this agreement or in any disclosures made hereunder shall create or imply, or be construed as to grant to the Receiving Party any license or other rights in or to the Confidential Information and/or any intellectual property rights attached thereto, or act as a waiver of any rights that the Disclosing Party may have to prevent infringement or misappropriation of any patents, patent applications, trademarks, copyright, trade secrets, know-how or other intellectual property rights owned or controlled by the Disclosing Party as at the Effective Date.
- 6.3 The Disclosing Party provides the Confidential Information "as is" and accordingly no disclosure thereof by it hereunder shall constitute any representation, warranty, assurance, guarantee or inducement by such Disclosing Party with respect to infringement of patents or other rights of third parties, nor is any warranty or representation as to the accuracy, completeness, or technical or scientific quality of any of the Disclosing Party's Confidential Information provided hereunder. (For the avoidance of doubt it is stated expressly that the Disclosing Party neither makes, nor have made, any representation or warranty as to the merchantability or fitness for a particular purpose

of any Confidential Information disclosed hereunder).

#### 7 Term of Obligation

7.1 The Parties' obligations concerning non-disclosure of Confidential Information contained in the above clauses shall commence on the Effective Date and shall continue for five (5) years from the date of each disclosure, unless otherwise agreed between the parties in writing, where after such obligations shall forthwith terminate.

#### 8 No Violation

8.1 Each party represents that its compliance with the provisions of this agreement will not violate any duty which such party may have towards any third party, including obligations concerning the provision of services to others, confidentiality of information and assignment of inventions, ideas, patents or copyright.

#### 9 Breach

9.1 It is acknowledged that the breach of this agreement by the Receiving Party would cause the Disclosing Party irreparable injury not compensable in monetary damages alone. Accordingly, in the event of a breach, or a threat of a breach, the Disclosing Party, in addition to its other remedies, is entitled to a restraining order, preliminary injunction or similar relief so as to specifically enforce the terms of this agreement or prevent, cure or reduce the adverse effects of the breach.

### 10 DOMICILIUM CITANDI ET EXECUTANDI

10.1 The Parties hereto respectively choose as their domicilium citandi et executandi for all purposes of, and in connection with this agreement, the physical addresses and contact details stated herein.

## 11 Notices

11.1 Any Notice to be given hereunder shall be given in writing and may be given either personally or may be sent by post or facsimile and addressed to the relevant party at its domicilium citandi et executandi address as chosen herein. Any notice given by post shall be deemed to have been served on the expiry of 7 (seven) working days after same is posted by recorded delivery post or air mail. Any notice delivered personally or sent by facsimile shall be deemed to have been served at the time of delivery or sending.

#### 12 Governing Law and Jurisdiction

12.1 This agreement will be governed and construed by the laws of the Republic of South Africa and the Parties hereby submit to the exclusive jurisdiction of the South African courts to hear any dispute arising therefrom which the Parties are unable to settle amicably.

#### 13 General

- 13.1 This agreement comprises the entire agreement between the parties concerning the subject matter and supersedes all prior oral and written agreements between them.
- 13.2 No waiver, alteration or cancellation of any of the provisions of the Agreement shall be binding unless made in writing and signed by the party to be bound.
- 13.3 The parties hereby warrant that the officials signing this agreement have the power to do so on behalf of the parties.
- 13.4 No public announcement, such as a media release, or disclosure beyond those disclosures authorised for Confidential Information hereunder may be made by either party concerning this agreement without the prior written approval of the other party.
- 13.5 Neither party is, by virtue agreement, authorised to use the name, logo(s) or trademarks of the other in connection with any advertising, publicity, marketing or promotional materials or activities, or for any other purpose whatsoever, without the prior written consent of the other party. For purposes of this clause, it is also recognised that, under the provisions of section 15 (1) of the Merchandise Marks Act, Act No 17 of 1941 of the Republic of South Africa, the use of the abbreviation of the name of the Council for Scientific and Industrial Research, "WNNR" and CSIR, is prohibited in connection with any trade, business, profession or occupation or in connection with a trade mark, mark or trade description applied to goods, other than with the consent of the CSIR.
- 13.6 Both Parties shall remain free to use, in the normal course of its business, its general knowledge, skills and experience incurred before, during or after the discussions envisaged hereunder. (To this end, it is also recorded that nothing in this Agreement shall be construed as constituting an exclusive arrangement between the parties and both Parties shall remain free to explore market opportunities in the Field, unless otherwise agreed to in writing in a subsequent agreement.)

## ANNEXURE K: MUTUAL NDA

## Parties to the NDA

| <b>THE CSIR</b> , a statutory council, duly established under Act 46 of 1988 through its Operating Unit |
|---|
| ofin his/her capacity as  |
| Executive Director and he/ she being duly authorised thereto; and                                       |
|   |
|   |
| , registration number: a  |
| with limited liability duly incorporated under the applicable laws of the Republic of South Africa      |
| herein represented by in his/her  |
| capacity as and   |
| he/she being duly authorised thereto.   |
| 2 Contact Details for Purposes of Clause 10:  |
| 2.1 The CSIR  |
| Physical Address:   |
|   |
| Meiring Naude Road  |
| Meiring Naude Road Brummeria  |
| •   |
| Brummeria   |
| Brummeria Pretoria  |
| Brummeria Pretoria 0002   |
| Brummeria Pretoria 0002 FOR ATTENTION:  |

Telefax Communication:

Request for Proposal CSIR RFP No.: 1117.1/03/11/2023

| FOR ATT    | TENTION:            |                                      |
|------------|---------------------|--------------------------------------|
|            |                     |                                      |
| Physical A | Address:            |                                      |
| FOR ATT    | TENTION:            |                                      |
| Postal Ad  | ddress:             |                                      |
| FOR ATT    | TENTION:            |                                      |
| Telefax C  | Communication:      |                                      |
| FOR ATT    | TENTION:            |                                      |
| 3 Effec    | ctive Date:         |                                      |
| J LIIEC    | Cuve Date           |                                      |
| 4 THE      | FIELD:              |                                      |
|            | ON THIS THEDAY OFAT | T IN THE PRESENCE OF THE             |
| 1.         |                     |                                      |
| 2.         |                     |                                      |
|            |                     |                                      |
|            | ON THIS THEDAY OFAT | FOR THE CSIR TIN THE PRESENCE OF THE |
| 1.         |                     |                                      |
| 2.         |                     |                                      |
|            |                     |                                      |

Request for Proposal CSIR RFP No.: 1117.1/03/11/2023

FOR XXXX