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Tender

UK Approved Body for In Vitro Diagnostic (IVD) Devices

MHRA/ NIBSC

F02: Contract notice
Notice identifier: 2023/S 000-034981
Procurement identifier (OCID): ocds-h6vhtk-041d1b
Published 27 November 2023, 5:18pm

Section I: Contracting authority

I.1) Name and addresses

MHRA/ NIBSC

EN6 3QG

London

EN6 3QG

Contact

Alison Finn

Email

Alison.finn@mhra.gov.uk

Country

United Kingdom

Region code

UK - United Kingdom

National registration number

MHRA Buyer Organisation

Internet address(es)

Main address

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Buyer's address

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

I.3) Communication

The procurement documents are available for unrestricted and full direct access, free of charge, at

https://health-family.force.com/s/Welcome

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

https://health-family.force.com/s/Welcome

Tenders or requests to participate must be submitted to the above-mentioned address

Electronic communication requires the use of tools and devices that are not generally available. Unrestricted and full direct access to these tools and devices is possible, free of charge, at

https://health-family.force.com/s/Welcome

I.4) Type of the contracting authority

Ministry or any other national or federal authority

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

UK Approved Body for In Vitro Diagnostic (IVD) Devices

Reference number

C171048

II.1.2) Main CPV code

- 79132000 - Certification services

II.1.3) Type of contract

Services

II.1.4) Short description

The Medicines and Healthcare products Regulatory Agency requires a UK Approved Body that is capable of certifying IVD devices produced by Scientific Research and Innovation that are placed on the GB market.

II.1.5) Estimated total value

Value excluding VAT: £500,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

II.2.4) Description of the procurement

Scientific Research and Innovation (SR&I) (previously known as NIBSC) is placing In Vitro Diagnostic (IVD) devices on the GB market under EU IVD Directive 98/79/EC using EU Notified Body that issues CE certificates that are currently recognised on the GB market. Since 1 January 2021, there have been a number of changes to Medical Devices Regulations 2002, introduced through secondary legislation - Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, to how medical devices, including IVD devices, are placed on the market in Great Britain (England, Wales and Scotland).
Due to the changes, SR&I must appoint a UK Approved Body that can certify all Annex II List A and B IVD devices produced by SR&I that are placed on the GB market.
This appointment will allow SR&I to continue placing IVD devices on the GB market after transition deadlines and support NHS and NHSBT laboratories and other diagnostic laboratories in safeguarding patients' health and wellbeing.

II.2.5) Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.7) Duration of the contract, framework agreement or dynamic purchasing system

Start date

1 February 2024

End date

31 January 2027

This contract is subject to renewal

Yes

Description of renewals

two optional one-year extensions

II.2.10) Information about variants

Variants will be accepted: No

II.2.11) Information about options

Options: No

II.2.13) Information about European Union Funds

The procurement is related to a project and/or programme financed by European Union funds: No

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Section III. Legal, economic, financial and technical information

III.1) Conditions for participation

III.1.1) Suitability to pursue the professional activity, including requirements relating to enrolment on professional or trade registers

List and brief description of conditions

UK approved bodies listed under Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

III.1.3) Technical and professional ability

Selection criteria as stated in the procurement documents

III.2) Conditions related to the contract

III.2.2) Contract performance conditions

UK approved bodies listed under Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Open procedure

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: Yes

IV.2) Administrative information

IV.2.2) Time limit for receipt of tenders or requests to participate

Date

10 January 2024

Local time

12:00pm

IV.2.4) Languages in which tenders or requests to participate may be submitted

English

IV.2.6) Minimum time frame during which the tenderer must maintain the tender

Duration in months: 2 (from the date stated for receipt of tender)

IV.2.7) Conditions for opening of tenders

Date

10 January 2024

Local time

12:00pm

Section VI. Complementary information

VI.1) Information about recurrence

This is a recurrent procurement: Yes

VI.4) Procedures for review

VI.4.1) Review body

High Court

39 Victoria Street

London

SW1H 0EU

Country

United Kingdom

Internet address

https://www.gov.uk/government/organisations/department-of-health-and-social-care

VI.4.2) Body responsible for mediation procedures

High Court

39 Victoria Street

London

SW1H 0EU

Country

United Kingdom

Internet address

https://www.gov.uk/government/organisations/department-of-health-and-social-care