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Tender

## **EU Notified Body designated under Regulation (EU) 2017/746 (IVDR)**

NHS Blood and Transplant

UK4: Tender notice - Procurement Act 2023 - [view information about notice types](#)

Notice identifier: 2025/S 000-011644

Procurement identifier (OCID): ocds-h6vhtk-04e9b4 ([view related notices](#))

Published 27 March 2025, 4:58pm

### **Scope**

### **Description**

NHS Blood and Transplant (NHSBT) is seeking to engage with an EU Notified Body designated under Regulation (EU) 2017/746 (IVDR) to undertake conformity assessment of in vitro diagnostic medical devices (IVDs) and appropriate surveillance of legacy IVDs. NHSBT is a Special Health Authority that provides a blood and transplantation service to the NHS, looking after blood donation services in England and transplant services across the UK. NHSBT Reagents is a specialist department within NHSBT that designs, manufactures and distributes in vitro diagnostic medical devices for transfusion and transplantation investigations including blood grouping control reagents. NHSBT's current EU Notified Body has not been designated under the IVDR and we require the services of an alternative EU Notified Body for conformity assessment and CE-certification of IVDs under the IVDR, and for appropriate surveillance of legacy IVDs (i.e. IVDs that are covered by a certificate issued by a Notified Body in accordance with Directive 98/79/EC (IVDD) and which comply with the conditions set out in Article 110 (3c) of the IVDR). It is imperative that NHSBT is able to lodge a formal application for conformity assessment and sign a written agreement with an alternative EU Notified Body in accordance with deadlines set out in the Article 110 (3c) point (e) and Article 110 (3c) point (f) of the IVDR, respectively. This will enable NHSBT to benefit from the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860. The device risk

class, IVDR transitional deadlines and number of devices / products are summarised in the tender documents. The EU Notified Body's designation must cover the scope of designation applicable to the IVDs manufactured by NHSBT which is summarised as follows:

- NBOG Codes that apply to legacy devices; IVD0101, IVD0102, IVD0302, MDS7210.
- IVDR Codes that apply to the IVDR devices; IVR0101, IVR0102, IVR0103, IVR0104, IVR0105, IVR0106, IVS1004, IVT2006, IVT2008, IVT2009, IVT2011, IVP3001, IVP3006 (note: not all codes apply to all devices).

NHSBT's requirements are summarised below:

- Surveillance assessment of legacy devices during the transitional period.
- Assessment of NHSBT's Quality Management System.
- Undertake announced and unannounced audits.
- Conformity assessment and CE-certification of NHSBT's IVDs.
- Surveillance assessment of IVDR CE-certified IVDs (following initial certification).
- Batch / product verification for Class D devices.
- Validate the Summary of Safety and Performance for Class D and C devices.
- Assess and approve (or reject) proposed/planned substantial changes to NHSBT Reagents product range, products or Quality Management System.

### **Total value (estimated)**

- £160,000 excluding VAT
- £192,000 including VAT

Above the relevant threshold

### **Contract dates (estimated)**

- 26 May 2025 to 25 May 2027
- Possible extension to 25 May 2029
- 4 years

Description of possible extension:

2 x 12 monthly or cumulative extension to a maximum 4 year contract

## **Options**

The right to additional purchases while the contract is valid.

2 x 12 monthly or cumulative extension to a maximum 4 year contract

## **Main procurement category**

Services

## **CPV classifications**

- 72225000 - System quality assurance assessment and review services
- 71630000 - Technical inspection and testing services

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## **Submission**

### **Enquiry deadline**

16 April 2025, 12:00pm

### **Tender submission deadline**

24 April 2025, 12:00pm

### **Submission address and any special instructions**

<https://atamis-1928.my.site.com/s/Welcome>

**Tenders may be submitted electronically**

Yes

**Languages that may be used for submission**

English

**Award decision date (estimated)**

6 May 2025

**Recurring procurement**

Publication date of next tender notice (estimated): 1 January 2029

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**Award criteria**

<b>Name</b>	<b>Type</b>	<b>Weighting</b>
Price	Price	60.00%
Quality	Quality	30.00%
Social Value	Quality	10.00%

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**Other information****Payment terms**

30 day payment terms, paid monthly based on services provided

## Description of risks to contract performance

Due to the nature of the contract and the unknown hours of work that may be required to undertake the assessments, there is a risk that the predicted whole life costs used to calculate the potential contract value may be exceeded.

## Applicable trade agreements

- Government Procurement Agreement (GPA)

## Conflicts assessment prepared/revised

Yes

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## Procedure

### Procedure type

Open procedure

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## Contracting authority

### NHS Blood and Transplant

- Public Procurement Organisation Number: PDBY-6395-VWBP

500 North Bristol Park

Bristol

BS34 7QH

United Kingdom

Contact name: Rowena Thomas

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Email: [rowena.thomas@nhsbt.nhs.uk](mailto:rowena.thomas@nhsbt.nhs.uk)

Website: <https://www.nhsbt.nhs.uk/>

Region: UKK12 - Bath and North East Somerset, North Somerset and South Gloucestershire

Organisation type: Public authority - central government