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Award

Transfusion Technology Products - LOVO instrument – med device CE marked

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

UK5: Transparency notice - Procurement Act 2023 - <u>view information about notice types</u> Notice identifier: 2025/S 000-008323 Procurement identifier (OCID): ocds-h6vhtk-04ea6f Published 7 March 2025, 11:51am

Scope

Reference

C340408

Description

Advanced Therapies service for 2x LOVO systems. Direct Award Section 41, Schedule 5 - The justification is an absence of competition and technical reasons. CRCR240163

Contract 1. Transfusion Technology Products - LOVO instrument

- med device CE marked

Suppliers

Supplier not yet selected

Contract value

- £188,000 excluding VAT
- £225,600 including VAT

Above the relevant threshold

Earliest date the contract will be signed

20 March 2025

Contract dates (estimated)

- 21 March 2025 to 20 March 2026
- 1 year

Main procurement category

Goods

CPV classifications

• 33100000 - Medical equipments

Other information

Conflicts assessment prepared/revised

Yes

Procedure

Procedure type

Direct award

Direct award justification

Single supplier - technical reasons

 The LOVO MED is the only commercially available device with the correct level of CE Marking and the capability to handle all the techniques and processes our department requires. Alternatives on the market, would require the purchase of two different devices to cover the array of processes. • The LOVO system is tailored for larger volume applications, while the Cue system is optimized for small-volume processes. While there are only one or two alternative manufacturers in the field (or world) Fresenius Kabi's LOVO and Cue machines are specialised in the volumes they treat. • The choice of LOVO and Cue by CGT specialists has been based on Fresenius Kabi's systems due to the demand on specific criteria, such as volume capacity, automation level, and integration capabilities. • Fresenius Kabi's Cell and Gene therapy is unique in that it requires advanced biological, genetic, and engineering expertise. It is not a standard piece of equipment that sees many vendors. It involves complex processes such as gene editing, stem cell manipulation, and immune cell reprogramming, which demand specialized equipment and regulatory compliance. • Strict regulations from agencies like the FDA (U.S.), EMA (Europe), and MHRA (UK) govern CGT manufacturing, requiring companies to meet rigorous compliance standards. The regulatory involvement does put off many other manufacturers wishing to develop in this field due to such high focused

compliance standards. • The market for CGT is still emerging, with fewer patients receiving these therapies compared to traditional drug treatments. As CGT adoption grows, demand for automated, closed-system collection and processing equipment will maybe increase. This could lead to more competition and innovation, but for now the choice is extremely limited and we are currently the devices of choice in this field.

Contracting authority

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

• Public Procurement Organisation Number: PDCY-5582-YRHQ

Regent Point

NEWCASTLE UPON TYNE

NE7 7DN

United Kingdom

Email: helen.potts18@nhs.net

Website: https://www.newcastle-hospitals.nhs.uk

Region: UKC22 - Tyneside

Organisation type: Public authority - central government