# EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

## MDR 780152 R000

**Manufacturer:** DTR Medical Ltd

**Address:**
17 Clarion Court
Clarion Court Enterprise Park
Swansea
SA6 8RF
United Kingdom

**Single Registration Number:** GB-MF-000023112

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-03-14**

Current Issue Date: **2024-12-12**

Starting Validity Date: **2024-12-12**

Expiry Date: **2029-03-13**

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### Device Schedule: Class IIa, Custom-made and other devices

| Device(s) | Risk Classification |
|---|---|
| Surgical drainage systems | Class IIa |
| Forceps – ENT, suture and dissecting, arterial | Class IIa |
| Oral biopsy forceps / oral rotating biopsy punch | Class IIa |
| Cervical biopsy punch | Class IIa |
| Gynaecological devices | Class Is |
| For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. | |

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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

| Date | Reference Number | Action |
|---|---|---|
| 2024-03-14 | 3785743 | Issued |
| 2024-04-09 | 30159159 | Amended – addition of critical subcontractor for manufacture of surgical drainage systems |
| Current | 30245831 | Supplemented – addition of:<br>Forceps – ENT, suture and dissecting, arterial, Oral biopsy forceps / oral rotating biopsy punch Cervical biopsy punch |

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