

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 751413 R000

**Manufacturer:** Pioneer Surgical Technology Inc.

**Address:**

375 River Park Circle  
Marquette  
Michigan  
49855  
USA

**Single Registration Number:** US-MF-000010369

**EU Authorised Representative:** Tutogen Medical GmbH

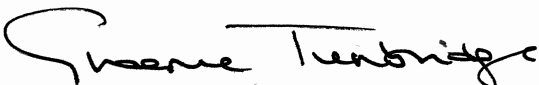
**Address:**

Industriestraße 6  
91077 Neunkirchen am Brand  
Germany

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

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II 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 Medical Devices

First Issue Date: **2022-11-24**

Current Issue Date: **2022-11-24**

Starting Validity Date: **2022-11-24**

Expiry Date: **2027-11-23**

...making excellence a habit.™

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 751413 R000

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

Device(s)	Risk Classification
Reusable Instruments 'Orthopaedic Instruments'	Class Ir
Reusable Instruments 'General Surgery Instruments'	Class Ir

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.



First Issue Date: **2022-11-24**

Current Issue Date: **2022-11-24**

Starting Validity Date: **2022-11-24**

Expiry Date: **2027-11-23**

...making excellence a habit.™

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 751413 R000

### 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
Current	3449895	Issued



First Issue Date: **2022-11-24**

Current Issue Date: **2022-11-24**

Starting Validity Date: **2022-11-24**

Expiry Date: **2027-11-23**

...making excellence a habit.™

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.