

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: MDSS GmbH

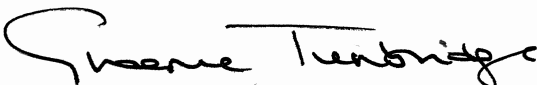
Address:

Schiffgraben 41
Hannover
30175
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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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 Global Regulatory & Quality

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

Current Issue Date: **2026-02-02**

Starting Validity Date: **2026-02-02**

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

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Page 1 of 3

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.

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Device Schedule: Class III and Class IIb devices

Class IIb, Implantable, Well-established technologies	Intended purpose
Bone fixation wires	Intended for temporary fixation and/or stabilization of skeletally mature bone in orthopedic trauma and reconstructive surgery
Bone fixation plates	Intended for temporary fixation and/or stabilization of skeletally mature bone in orthopedic trauma and reconstructive surgery

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

Device(s)	Risk Classification
Orthopaedic instruments connected to active device, non-sterile	Class IIa
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.	

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Page 2 of 3

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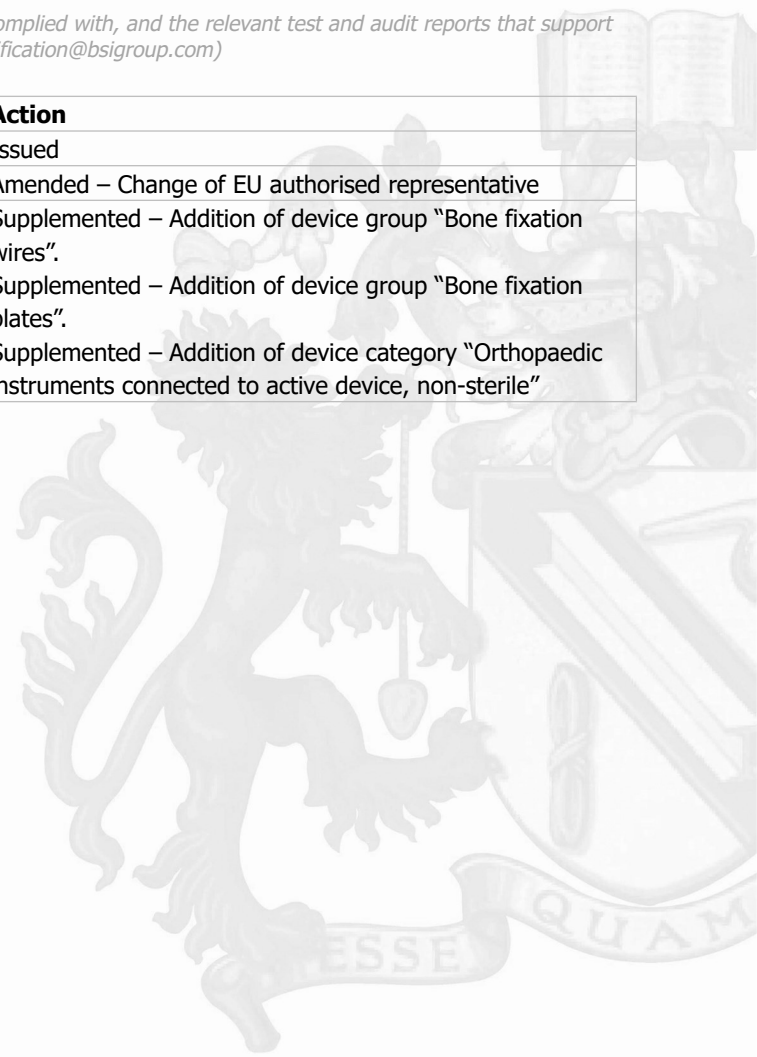
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Certificate History

(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
2022-11-24	3449895	Issued
2025-10-27	30538943	Amended – Change of EU authorised representative
Current	30611219	Supplemented – Addition of device group “Bone fixation wires”. Supplemented – Addition of device group “Bone fixation plates”. Supplemented – Addition of device category “Orthopaedic instruments connected to active device, non-sterile”



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Page 3 of 3

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