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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 52820**

Issued To: **Pioneer Surgical Technology Inc.**
375 River Park Circle
Marquette
Michigan
49855
USA

In respect of:

The design and manufacture of Porcine gelatin-based resorbable biological synthetic bone graft substitutes, sterile Hip fixation implants, non-sterile Orthopaedic bone screw and washer implants, sterile Orthopaedic fixation cerclage wire/cable implant, sterile and non-sterile Spinal fixation cable implant, sterile and non-sterile Sternal fixation cable/plate implants, non-sterile non-cervical Intervertebral spinal fusion implants, sterile Interbody fusion implants, sterile Interspinous lumbar decompression spacer implant and non-sterile instruments intended for connection to an active medical device and non-sterile single-use instruments.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1999-11-29** Date: **2020-11-13** Expiry Date: **2024-05-26**

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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 52820

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Number	Device Name	Intended purpose per IFU
Class III		
MD 0202 MDS 7009 MDS 7002	NanOss Bioactive Porcine Gelatin Resorbable Bone Void Filler	See CE 567423
MD 0202 MDS 7009 MDS 7002	NanoOss Bioactive 3D Bone Void Filler	See CE 651190
Class IIb		
61325	Bone-screw internal spinal fixation system	Intervertebral spinal fixation implant system, for non-cervical indications
60847	Spinal fusion cage	Interbody fusion implant
34017	Sternal Fixation system	Internal sternal fixation implant
61531	Lumbar Interspinous spacer	Interspinous decompression spacer implant for lumbar indications
61690	Hex Button	Internal orthopaedic fixation cerclage wire/cable implant
44797 61465	Spinal fixation cable system	Internal spinal cable fixation implant system
56642 61670	Orthopaedic bone screw and washer system	Orthopedic bone fixation implant system
34003	Hip internal fixation system (GTR-Great Trochanteric Reattachment)	Hip fixation implant
60847	3D printed PEKK interbody spinal fusion cages	Cervical Interbody Fusion, Lumbar Interbody Fusion, 1 or 2 contiguous levels for Spondylolisthesis or degenerative disc disease

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Single-use orthopaedic instruments	Orthopedic manual surgical instrument, single use
MD 0106	Reusable instruments connect to an active device	Orthopaedic surgical instruments connected to active device, Reusable, Invasive (transient use)

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