



### **UKCA Design-Examination Certificate**

Part II of The Medical Devices Regulations 2002, Annex II Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No.

Issued To:

UKCA 778539

Pioneer Surgical Technology Inc 375 River Park Circle Marquette Michigan 49855 USA

In respect of:

#### Absorbable porcine gelatin nanOss Bioactive 3D Bone Void Filler

BSI has performed a design examination of the above devices in accordance with Part II of The Medical Devices Regulations 2002, Annex II Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The design conforms to the requirements of this regulation. For the placing on the market of these products an Annex II (modified as described above) excluding Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: 2022-11-18

Date: 2022-11-18

Expiry Date: 2026-08-07

...making excellence a habit."

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000 Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK. A member of BSI Group of Companies.





## **UKCA Design-Examination Certificate**

#### **Supplementary Information to UKCA 778539**

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**Intended Purpose as per the Instructions for Use:** nanOss Bioactive 3D is intended for bony voids or gaps that are not intrinsic to the stability of bony structure.

#### **Classification: III**

Catalogue Number	Device Name	Model, Type
90-300-25504E	nanOss Bioactive 3D Bone Void Filler	25x50x4mm, 5cc
90-300-251004E	nanOss Bioactive 3D Bone Void Filler	25x100x4mm, 10cc
90-300-25508E	nanOss Bioactive 3D Bone Void Filler	25x50x8mm, 10cc
90-300-251008E	nanOss Bioactive 3D Bone Void Filler	25x100x8mm, 20cc

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# **Certificate History**

Date	Reference Number	Action	
Current	3757150	First Issue, Traceable to CE 651190	

First Issued: 2022-11-18

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