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. **UKCA 778539**

Issued To: **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**

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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

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