

# EC Design-Examination Certificate

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

**No.** CE 651190  
Issued To: **Pioneer Surgical Technology Inc.**  
**375 River Park Circle**  
**Marquette**  
**Michigan**  
**49855**  
**USA**

In respect of:

**nanoOss Bioactive 3D Bone Void Filler**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2016-08-08**

Date: **2021-05-13**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive 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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

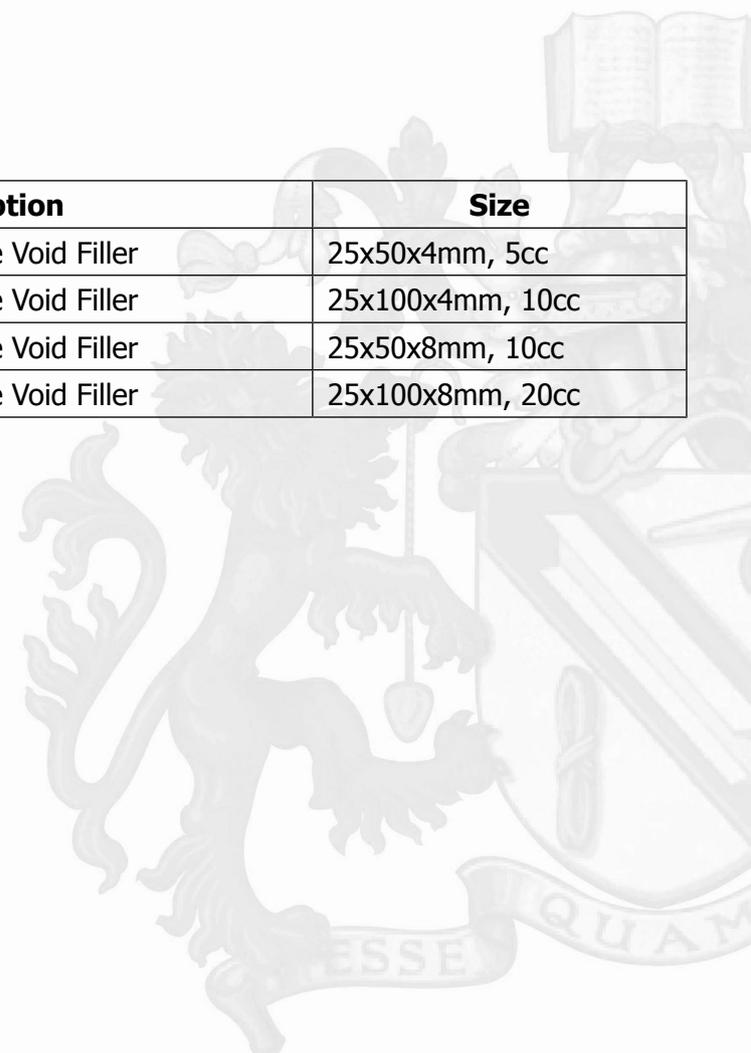
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Part Number	Description	Size
90-300-25504E	nanOss Bioactive 3D Bone Void Filler	25x50x4mm, 5cc
90-300-251004E	nanOss Bioactive 3D Bone Void Filler	25x100x4mm, 10cc
90-300-25508E	nanOss Bioactive 3D Bone Void Filler	25x50x8mm, 10cc
90-300-251008E	nanOss Bioactive 3D Bone Void Filler	25x100x8mm, 20cc



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## Certificate History

Date	Reference Number	Action
08 August 2016	10162078	First issue.
05 February 2019	7781001	Traceable to NB 0086.
Current	3267621	Certificate Renewal.

First Issued: **2016-08-08**

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