

EC Design-Examination Certificate

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

No.**CE 646685****Issued To:**

TEKNIMED SAS
8 rue du Corps Franc-Pommiès
Vic En Bigorre
65500
France

In respect of:

ORCEM – Surgical cement with Gentamicin

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: 2017-09-15**Date: 2021-03-03****Expiry Date: 2022-12-13**

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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.

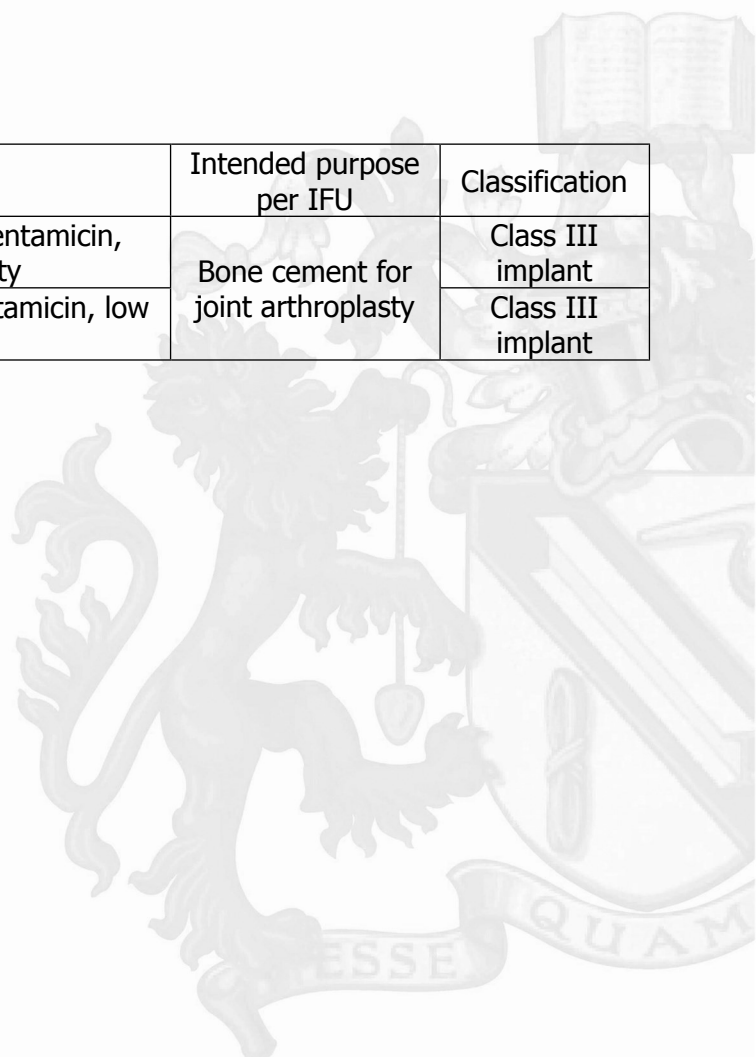
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Supplementary Information to CE 646685

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Catalogue Number	Device Name	Model, type	Intended purpose per IFU	Classification
17.0101	ORCEM 1G	Surgical cement with Gentamicin, standard viscosity	Bone cement for joint arthroplasty	Class III implant
17.0102	ORCEM 3G	Surgical cement with Gentamicin, low viscosity		Class III implant

First Issued: **2017-09-15**Date: **2021-03-03**Expiry Date: **2022-12-13**

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Certificate History

Date	Reference Number	Action
15 September 2017	8776163	First issue, Mirror Certificate of CE 646675.
15 December 2017	8802845	Certificate Renewal.
09 January 2019	8716039	Traceable to NB 0086.
19 February 2019	9656191	Certificate Renewal.
Current	3256204	Indication for use extended to include primary surgeries

First Issued: **2017-09-15**Date: **2021-03-03**Expiry Date: **2022-12-13**

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

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