

EC TYPE-EXAMINATION CERTIFICATE

Number: 87754TE11

Directive 93/42/EEC on Medical devices, Annex III
(Devices in Class IIb and III)

Manufacturer:

European Medical Contract Manufacturing B.V.
Middenkampweg 17
6545 CH Nijmegen
The Netherlands

For the product / product category

Acrylic orthopaedic cements with gentamicin (Class III):
Genta C~ment 1
Genta C~ment 1 2x20
Genta C~ment 3

Documents, that form the basis of this certificate:

Certification Notice 87754CN, initially dated 1 July 1998

DEKRA hereby certifies that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex III (4) of this Directive.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 March 2018
Issued for the first time: 1 March 2001
Reissued: 1 March 2015

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

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