

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2221348DE01

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

G21 S.r.l.
Via S. Pertini 8
41039 San Possidonio
Italy

For the product

Sterile radio-opaque bone cement (PMMA) with antibiotic (Gentamicin Sulphate) intended for fixation of orthopedic implants to the bone

Documents, that form the basis of this certificate:

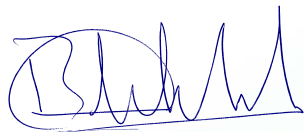
Certification Notice 2221348CN, initially dated 29 December 2019
CE Marking of Conformity 2221348CE01
Addendum, initially dated 2 January 2020

DEKRA hereby declares that the design 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 II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

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: 26 May 2024
Issued for the first time: 2 January 2020

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized initials and a surname.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, consisting of stylized initials and a surname.

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2221348DE01

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Sterile radio-opaque bone cement (PMMA) with antibiotic (Gentamicin Sulphate) intended for fixation of orthopedic implants to the bone

Issued to:

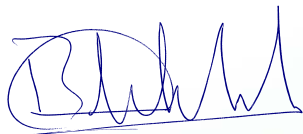
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Via S. Pertini 8
41039 San Possidonio
Italy

This certificate covers the following product(s):

- G1A – Std viscosity (Models 20, 40)
- G3A – Low viscosity (Models 20, 40, 60)
- Genta Cement Oliga 1 – Std viscosity (Models 20, 40)
- Genta Cement Oliga 3 – Low viscosity (Models 20, 40, 60)

Initial date: 2 January 2020

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of a stylized, cursive script.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized, cursive script.

J.A. van Vugt
Certification Manager

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