By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

GC Europe N.V.
Research Park
Interleuvenlaan 33
Leuven
B-3001
Belgium

Holds Certificate Number: **MD 83628**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The Manufacture and distribution of dental restorative, orthodontic, prosthetic, fibre reinforced, periodontal materials, dental scanner and associated accessories, dental restorative materials for CAD/CAM technologies and dental in-vitro diagnostic devices and distribution and service of dental equipment.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2005-01-11
Effective Date: 2023-01-11
Latest Revision Date: 2023-01-10
Expiry Date: 2026-01-10

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Certificate of Registration

OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEM - ISO 45001:2018

This is to certify that:

GC Europe N.V.
Interleuvenlaan 33
B-3001 Leuven
Belgium

Holds Certificate No: **OHS 87309**

and operates an Occupational Health and Safety Management System which complies with the requirements of ISO 45001:2018 for the following scope:

The production, packaging, distribution and after sales, assistance of dental restorative, orthodontic, prosthetic, periodontal materials, equipment and associated accessories, milling services and dental in vitro diagnostic devices. The provision of educational services to dental community.

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2006-03-07
Latest Revision Date: 2020-02-12

Effective Date: 2020-02-12
Expiry Date: 2023-02-11

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Certificate No: **OHS 87309**

Location	Registered Activities
GC Europe N.V. Interleuvenlaan 33 B-3001 Leuven Belgium	The production, packaging, distribution and after sales, assistance of dental restorative, orthodontic, prosthetic, periodontal materials, equipment and associated accessories, milling services and dental in vitro diagnostic devices. The provision of educational services to dental community.
GC Manufacturing Europe N.V. Interleuvenlaan 13 B-3001 Leuven Belgium	The production, packaging, distribution and after sales, assistance of dental restorative, orthodontic, prosthetic, periodontal materials, equipment and associated accessories, milling services and dental in vitro diagnostic devices. The provision of educational services to dental community.

Original Registration Date: 2006-03-07
Effective Date: 2020-02-12
Latest Revision Date: 2020-02-12
Expiry Date: 2023-02-11

Certificate of Registration

ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that:

GC Europe N.V.
Interleuvenlaan 33
B-3001 Leuven
Belgium

Holds Certificate No: **EMS 87308**

and operates an Environmental Management System which complies with the requirements of ISO 14001:2015 for the following scope:

The production, packaging, distribution and after sales, assistance of dental restorative, orthodontic, prosthetic, periodontal materials, equipment and associated accessories, milling services and dental in vitro diagnostic devices. The provision of educational services to dental community.

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2005-09-28
Effective Date: 2020-02-16
Latest Revision Date: 2020-02-12
Expiry Date: 2023-02-15

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Certificate of Registration

OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEM - ISO 45001:2018

This is to certify that:

GC Europe N.V.
Interleuvenlaan 33
B-3001 Leuven
Belgium

Holds Certificate No: **OHS 87309**

and operates an Occupational Health and Safety Management System which complies with the requirements of ISO 45001:2018 for the following scope:

The production, packaging, distribution and after sales, assistance of dental restorative, orthodontic, prosthetic, periodontal materials, equipment and associated accessories, milling services and dental in vitro diagnostic devices. The provision of educational services to dental community.

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2006-03-07
Latest Revision Date: 2020-02-12

Effective Date: 2020-02-12
Expiry Date: 2023-02-11

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Certificate No: **OHS 87309**

Location	Registered Activities
GC Europe N.V. Interleuvenlaan 33 B-3001 Leuven Belgium	The production, packaging, distribution and after sales, assistance of dental restorative, orthodontic, prosthetic, periodontal materials, equipment and associated accessories, milling services and dental in vitro diagnostic devices. The provision of educational services to dental community.
GC Manufacturing Europe N.V. Interleuvenlaan 13 B-3001 Leuven Belgium	The production, packaging, distribution and after sales, assistance of dental restorative, orthodontic, prosthetic, periodontal materials, equipment and associated accessories, milling services and dental in vitro diagnostic devices. The provision of educational services to dental community.

Original Registration Date: 2006-03-07
Effective Date: 2020-02-12
Latest Revision Date: 2020-02-12
Expiry Date: 2023-02-11

Certificate No: **EMS 87308**

Location	Registered Activities
GC Europe N.V. Interleuvenlaan 33 B-3001 Leuven Belgium	The production, packaging, distribution and after sales, assistance of dental restorative, orthodontic, prosthetic, periodontal materials, equipment and associated accessories, milling services and dental in vitro diagnostic devices. The provision of educational services to dental community.
GC Manufacturing Europe N.V. Interleuvenlaan 13 B-3001 Leuven Belgium	The production, packaging, distribution and after sales, assistance of dental restorative, orthodontic, prosthetic, periodontal materials, equipment and associated accessories, milling services and dental in vitro diagnostic devices. The provision of educational services to dental community.

Original Registration Date: 2005-09-28
Effective Date: 2020-02-16
Latest Revision Date: 2020-02-12
Expiry Date: 2023-02-15

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By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 01488**

Issued To: **GC Europe N.V.**
Research Park
Interleuvenlaan 33
Leuven
B-3001
Belgium

In respect of:

The manufacture of dental glass ionomer restorative systems, luting cements, fibre reinforcements, temporary filling, crown and bridge materials, conditioners, coating agents, composite resin and adhesive systems for direct and indirect restorations, temporary crown and bridge material, relining and periodontal dressing materials, ceramics, alloys and adhesives for dental applications.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1996-12-17** Date: **2019-04-25** Expiry Date: **2024-05-06**

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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.

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31385	Revisione / *Revision*	4
Primo rilascio / *First issue date*	2016-08-31	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

GC EUROPE N.V.

Sede Legale e Operativa / *Legal and Operative Site:*
Researchpark - Interleuvenlaan 33
Leuven -B-3001 - Belgio

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Dispositivo per la verifica della forza occlusale dentale / *Device for dental occlusal force test*
Materiale odontoiatrico per la realizzazione di ponti e corone temporanei stampabile con tecnologia 3D / *3D Printable light curing composite for temporary crown and bridge*
Vernice odontoiatrica ad applicazione topica per il trattamento dell'ipersensibilità / *Dental varnish topical application for the treatment of hypersensitivity*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Rif. rapporto di audit/ *Ref. audit report:* 02/12/2020

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* 23/03/2021

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:24/05/2021 11:21:20

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31385	Revisione / *Revision*	4
Primo rilascio / *First issue date*	2016-08-31	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivo per la verifica della forza occlusale dentale / *Device for dental occlusal force test*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 1111

Modello / Model:
Dental Prescale II

Tipologia / *Medical Devices:*
Materiale odontoiatrico per la realizzazione di ponti e corone temporanei stampabile con tecnologia 3D / *3D Printable light curing composite for temporary crown and bridge*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0402

Modello / Model:
GC TEMP PRINT

Codici / Codes:
901595/10004798, 901596/10004797

Tipologia / *Medical Devices:*
Vernice odontoiatrica ad applicazione topica per il trattamento dell'ipersensibilità / *Dental varnish topical application for the treatment of hypersensitivity*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0402

Modello / Model:
MI Varnish

Codici / Codes:
900746/10003389, 900747/10003390, 900748/10003391, 900749/10003392, 900750/10003393, 901460/10003xxx

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:24/05/2021 11:21:38

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
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E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31385	Revisione / *Revision*	4
Primo rilascio / *First issue date*	2016-08-31	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:24/05/2021 11:22:02

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

Certificate No: **MD 83628**

Location	Registered Activities
GC Europe N.V. Interleuvenlaan 33 Leuven B-3001 Belgium	Distribution of dental restorative, orthodontic, prosthetic, fibre reinforced, periodontal materials, dental equipment and associated accessories, dental restorative materials for CAD/CAM technologies and dental in-vitro diagnostic devices and Service of dental equipment.
GC Manufacturing Europe N.V. Interleuvenlaan 13 B-3001 Leuven Belgium	Production and packaging of dental restorative, orthodontic, prosthetic, fibre reinforced, periodontal materials, dental equipment and associated accessories, dental restorative materials for CAD/CAM technologies and dental in-vitro diagnostic devices.

Original Registration Date: 2005-01-11

Effective Date: 2023-01-11

Latest Revision Date: 2023-01-10

Expiry Date: 2026-01-10