EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 778483 R000

Manufacturer: GC Europe N.V.

Address:
Interleuvenlaan 33
3001 Leuven
Belgium

Single Registration Number: BE-MF-000001608

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-04-17**

Current Issue Date: **2026-02-06**

Starting Validity Date: **2026-02-06**

Expiry Date: **2030-04-16**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Implantable dental materials	Class IIa, implantable
Non-implantable dental materials	Class IIa

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation 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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2025-04-17	3756865	Issued.
Current	30605534	Supplemented – Addition of device group Implantable dental materials.

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