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

21st of June 2024

Notified Body Confirmation Letter

Reference: EU2023-607/771273

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

SRN Number: BE-MF-000001608

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
GC Fuji II LC (Improved) GC Fuji II LC CAPSULE	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji PLUS GC Fuji PLUS CAPSULE GC Fuji PLUST EWT	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji I CAPSULE GC Fuji I	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji BOND LC	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji BULK	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji ORTHO	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji ORTHO LC CAPSULE GC Fuji ORTHO LC	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji LINING LC	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji IX GP CAPSULE GC Fuji IX GP GC Fuji IX GP EXTRA GC Fuji IX GP FAST	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuj II CAPSULE GC Fuj II	Class IIa	N/A	CE 01488 issued by BSI (2797)
Miracle Mix CAPSULE Miracle Mix	Class IIa	N/A	CE 01488 issued by BSI (2797)
DENTIN CONDITIONER	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji PLUS CONDITIONER	Class IIa	N/A	CE 01488 issued by BSI (2797)
CAVITY CONDITIONER	Class IIa	N/A	CE 01488 issued by BSI (2797)
ORTHO CONDITIONER	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji COAT LC	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC FujiCEM	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji TRIAGE CAPSULE GC Fuji TRIAGE	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji VII CAPSULE	Class IIa	N/A	CE 01488 issued by BSI (2797)

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GC Fuji ORTHO BAND PASTE PAK	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji LINING LC PASTE PAK	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-COAT PLUS	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji VIII GP CAPSULE	Class IIa	N/A	CE 01488 issued by BSI (2797)
EQUIA (EQUIA Fil/EQUIA Coat)	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji ORTHO BAND LC PASTE PAK (Automix Compatible)	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji ORTHO LC PASTE PAK Automix	Class IIa	N/A	CE 01488 issued by BSI (2797)
ORTHO GEL CONDITIONER	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji TEMP LT	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC FujiCEM 2	Class IIa	N/A	CE 01488 issued by BSI (2797)
EQUIA Forte (EQUIA Forte Fil/EQUIA Forte Coat)	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC FujiCEM Evolve	Class IIa	N/A	CE 01488 issued by BSI (2797)
EQUIA Forte HT (EQUIA Forte HT Fil /EQUIA Forte Coat)	Class IIa	N/A	CE 01488 issued by BSI (2797)
FREEGENOL TEMPORARY PACK	Class IIa	N/A	CE 01488 issued by BSI (2797)
TEMPRON	Class IIa	N/A	CE 01488 issued by BSI (2797)
REBARON	Class IIa	N/A	CE 01488 issued by BSI (2797)
UNIFAST Trad	Class IIa	N/A	CE 01488 issued by BSI (2797)
UNIFAST III	Class IIa	N/A	CE 01488 issued by BSI (2797)
PATTERN RESIN LS	Class IIa	N/A	CE 01488 issued by BSI (2797)
UNIFAST LC	Class IIa	N/A	CE 01488 issued by BSI (2797)
CAVITON	Class IIa	N/A	CE 01488 issued by BSI (2797)
GRADIA	Class IIa	N/A	CE 01488 issued by BSI (2797)
GRADIA gum shades	Class IIa	N/A	CE 01488 issued by BSI (2797)
REVOTEK LC	Class IIa	N/A	CE 01488 issued by BSI (2797)

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GRADIA DIRECT	Class IIa	N/A	CE 01488 issued by BSI (2797)
GRADIA DIRECT X	Class IIa	N/A	CE 01488 issued by BSI (2797)
GRADIA DIRECT Flo GRADIA DIRECT LoFlo	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-BOND G-BOND Unit Dose	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-CEM CAPSULE	Class IIa	N/A	CE 01488 issued by BSI (2797)
OPTIGLAZE	Class IIa	N/A	CE 01488 issued by BSI (2797)
GRADIA CORE	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC KALORE	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-ænial	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-ænial Universal Flo	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-ænial Bond	Class IIa	N/A	CE 01488 issued by BSI (2797)
everStickC&B	Class IIa	N/A	CE 01488 issued by BSI (2797)
everStickORTHO	Class IIa	N/A	CE 01488 issued by BSI (2797)
everStickPERIO	Class IIa	N/A	CE 01488 issued by BSI (2797)
everStickPOST	Class IIa	N/A	CE 01488 issued by BSI (2797)
everStickNET	Class IIa	N/A	CE 01488 issued by BSI (2797)
everStickPOST INTRO	Class IIa	N/A	CE 01488 issued by BSI (2797)
Stick	Class IIa	N/A	CE 01488 issued by BSI (2797)
StickNET	Class IIa	N/A	CE 01488 issued by BSI (2797)
everX Posterior	Class IIa	N/A	CE 01488 issued by BSI (2797)
everStickINTRO	Class IIa	N/A	CE 01488 issued by BSI (2797)
CERASMART	Class IIa	N/A	CE 01488 issued by BSI (2797)
OPTIGLAZE color	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-ÆNIAL FLO X	Class IIa	N/A	CE 01488 issued by BSI (2797)
CERAMIC PRIMER II	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Initial CAST NP	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC KommonBase	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Ortho Connect	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC ETCHANT	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Ortho Etching Gel	Class IIa	N/A	CE 01488 issued by BSI (2797)

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GRADIA PLUS	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-Premio BOND	Class IIa	N/A	CE 01488 issued by BSI (2797)
Essentia	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Ortho Connect Flow	Class IIa	N/A	CE 01488 issued by BSI (2797)
METAL PRIMER Z	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Acrylic Primer	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-CEM LinkForce	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-Multi PRIMER	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC RELINE II	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Initial LiSi Press	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Initial LiSi Block	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-ænial Universal Injectable	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Modeling Liquid	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-CEM Veneer	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-ænial A'CHORD	Class IIa	N/A	CE 01488 issued by BSI (2797)
everX Flow	Class IIa	N/A	CE 01488 issued by BSI (2797)
CERASMART 270	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Aligner Connect	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC RELINE	Class IIa	N/A	CE 01488 issued by BSI (2797)
Solare Universal Bond	Class IIa	N/A	CE 01488 issued by BSI (2797)
Essentia HiFlo	Class IIa	N/A	CE 01488 issued by BSI (2797)
SOLARE Flo	Class IIa	N/A	CE 01488 issued by BSI (2797)
SOLARE X	Class IIa	N/A	CE 01488 issued by BSI (2797)
Essentia LoFlo	Class IIa	N/A	CE 01488 issued by BSI (2797)
Composite Primer	Class IIa	N/A	CE 01488 issued by BSI (2797)
Tempsmart DC	Class IIa	N/A	CE 01488 issued by BSI (2797)
G-CEM ONE	Class IIa	N/A	CE 01488 issued by BSI (2797)
G2-BOND UNIVERSAL	Class IIa	N/A	CE 01488 issued by BSI (2797)
Creation VC Make up Neo	Class IIa	N/A	CE 01488 issued by BSI (2797)
Creation VC Composite Primer	Class IIa	N/A	CE 01488 issued by BSI (2797)

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Creation VC FLOW Dentin	Class IIa	N/A	CE 01488 issued by BSI (2797)
Creation VC Ceramic Primer	Class IIa	N/A	CE 01488 issued by BSI (2797)
Creation VC Metal Primer	Class IIa	N/A	CE 01488 issued by BSI (2797)
Creation VC Veneering Composite	Class IIa	N/A	CE 01488 issued by BSI (2797)
Creation VC Gingiva	Class IIa	N/A	CE 01488 issued by BSI (2797)
Creation LS Press	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Initial	Class IIa	N/A	CE 01488 issued by BSI (2797)
Kooliner	Class IIa	N/A	CE 01488 issued by BSI (2797)
COE-PAK COE-PAK AUTOMIX NDS	Class IIa	N/A	CE 01488 issued by BSI (2797)
COE-COMFORT	Class IIa	N/A	CE 01488 issued by BSI (2797)
COE-SOFT	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fuji VII EP CAPSULE	Class IIa	N/A	CE 01488 issued by BSI (2797)
Fiber Post	Class IIa	N/A	CE 01488 issued by BSI (2797)
PATTERN RESIN	Class IIa	N/A	CE 01488 issued by BSI (2797)
SOFT-LINER	Class IIa	N/A	CE 01488 issued by BSI (2797)
Dry Mouth Gel	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC MI Paste Plus	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Tooth Mousse Plus	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Tooth Mousse	Class IIa	N/A	CE 01488 issued by BSI (2797)
GC Fiber Post Drill	Class IIa	N/A	CE 01488 issued by BSI (2797)
DIAPOLISHER PASTE	Class IIa	N/A	CE 01488 issued by BSI (2797)

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Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
GC TEMP PRINT	Class IIa	N/A	EC Certificate No. MED 31385 Expiry date: 2024-05-26 Notified Body Number 0476
MI Varnish	Class IIa	N/A	EC Certificate No. MED 31385 Expiry date: 2024-05-26 Notified Body Number 0476
Bite Force Analyzer (Dental Prescale II)	Class IIa	N/A	EC Certificate No. MED 31385 Expiry date: 2024-05-26 Notified Body Number 0476

Confirmation Letter Revision History

Date	Action
2024/01/26	Initial issue
2024/06/21	Addition of devices GC Fuji VII EP CAPSULE, Fiber Post, PATTERN RESIN, SOFT-LINER, Dry Mouth Gel, GC MI Paste Plus, GC Tooth Mousse Plus, GC Tooth Mousse, GC Fiber Post Drill, DIAPOLISHER PASTE in table 1 Addition of devices GC TEMP PRINT, MI Varnish and Bite Force Analyzer (Dental Prescale II) in table 2

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