GC Orthodontics Europe GmbH
Harkortstraße 2
58339 Breckerfeld
Germany

13th of March 2024

Notified Body Confirmation Letter

Reference: EU2023-607/810109

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 Orthodontics Europe GmbH
Harkortstraße 2
58339 Breckerfeld
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SRN Number: DE-MF-000009594

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withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

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
Metal Brackets ++E535MD0013L3 (Legend mini, Legend Medium, Axcess, Legacy, Legacy mini, Standard Edgewise)	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Self-ligating metal brackets ++E535MD0014L5 (Experience metal/Experience mini metal/ Experience L/LSB)	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Ceramic brackets ++E535MD0015L7 (Chic/Chic mini)	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Self-ligating ceramic brackets ++E535MD0016L9 (Experience ceramic/ Experience ceramic mini)	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Orthodontic bands ++E535MD0008LA (Sure snap/A-fit)	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Orthodontic wires ++E535MD0005L4 (Bio-active/Bio-active HI-ES/Initialloy/Initialloy HI-ES/Bio-edge/Stainless steel HI-ES/NiTi)	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Orthodontic Ligatures ++E535MD0010KV	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Orthodontic coil springs ++E535MD0003KY	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
GC Ortho Chain	Class IIa	N/A	EC Certificate No. CE 593589,

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
++E535MD0022L4			Expiry date: 26 May 2024 Notified Body Number 2797
Buccal tubes **++E535MD0006L6** (Legend/Axcess/Single tubes/Double tubes/Triple tubes/LP)	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Self-ligating Buccal tubes **++E535MD0007L8** (Experience)	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Lip Bumper **++E535MD0004L2**	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Lingual Sheath **++E535MD0009LC**	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Orthodontic Clasp **++E535MD0011KX**	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Palatal bar **++E535MD0018LD**	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Lingual retainer **++E535MD0019LF**	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Orthodontic hooks **++E535MD0020KY**	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Orthodontic stops **++E535MD0021L2**	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797
Auxilliary attachments - Lingual button, cleat, eyelet, seating lug **++E535MD0017LB**	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797

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
Welded components ++E535MD0023L6	Class IIa	N/A	EC Certificate No. CE 593589, Expiry date: 26 May 2024 Notified Body Number 2797

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
N/A	**N/A**	**N/A**	**N/A**

Confirmation Letter Revision History

Date	Action
2024/03/13	Initial issue