Dentscare Ltda.
Av. Edgar Nelson Meister, 474
Distrito Industrial
Joinville
89219-501
Brazil

2023-05-26

**Notified Body Confirmation Letter**
**Reference: EU2023-607/628678**

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:

Dentscare Ltda.
Av. Edgar Nelson Meister, 474
89219-501 Joinville
Brazil
SRN Number: BR-MF-000004013

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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.,

Digitally signed by Wendy Xia
Date: 2023.05.26 11:11:43 +01'00'

Wendy Xia

BSI Scheme Manager

**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 |
|---|---|---|---|
| **Nanosynt - 78996338BIO001WU** | Class III | N/A | CE 698954; NB 2797<br>CE 670390; NB 2797 |
| **ALLCEM (DUAL CEM) - 78996338CEM001VF** | Class IIa | N/A | CE 670390; NB 2797 |
| **ALLCEM CORE - 78996338CEM002VH** | Class IIa | N/A | CE 670390; NB 2797 |
| **ALLCEM VENEER APS - 78996338CEM003VK** | Class IIa | N/A | CE 670390; NB 2797 |
| **ORTHOCEM - 78996338CEM005VP** | Class IIa | N/A | CE 670390; NB 2797 |
| **ORTHO BITE - 78996338CEM006VR** | Class IIa | N/A | CE 670390; NB 2797 |
| **OPALLIS (ASTER) - 78996338RST003A4** | Class IIa | N/A | CE 670390; NB 2797 |
| **OPUS BULK FILL APS - 78996338RST005A8** | Class IIa | N/A | CE 670390; NB 2797 |
| **VITTRA APS - 78996338RST008AE** | Class IIa | N/A | CE 670390; NB 2797 |
| **VITTRA APS UNIQUE - 78996338RST009AG** | Class IIa | N/A | CE 670390; NB 2797 |
| **LLIS (SUPRAFIL+, MICROHYBRID+) - 78996338RST002A2** | Class IIa | N/A | CE 670390; NB 2797 |
| **OPALLIS FLOW (Aster Flow, Clinix Flow Composite) - 78996338RST004A6** | Class IIa | N/A | CE 670390; NB 2797 |
| **OPUS BULK FILL FLOW APS (Kent Bulk Fill Flow) - 78996338RST006AA** | Class IIa | N/A | CE 670390; NB 2797 |
| **BRAVA - 78996338RST0019Y** | Class IIa | N/A | CE 670390; NB 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 |
|---|---|---|---|
| **PRIMMAART - 78996338RST007AC** | Class IIa | N/A | CE 670390; NB 2797 |
| **AMBAR - 78996338ADS001VL** | Class IIa | N/A | CE 670390; NB 2797 |
| **AMBAR APS - 78996338ADS002VN** | Class IIa | N/A | CE 670390; NB 2797 |
| **AMBAR UNIVERSAL APS (K-BOND+UNIVERSAL, Simplee Universal Bond) - 78996338ADS003VQ** | Class IIa | N/A | CE 670390; NB 2797 |
| **WHITE POST - 78996338FGP001XZ** | Class IIa | N/A | CE 670390; NB 2797 |
| **ARCSYS FRICTIONAL IMPLANT - 78996338ACS002VB** | Class IIb excluding Class IIb implantable non-WET | N/A | CE 670390; NB 2797 |
| **FGM DRILLS - 78996338ACS001V9** | Class IIa | N/A | CE 670390; NB 2797 |
| **IMPLANT MOUTH DRIVER FOR HANDPIECE - 78996338ACS003VD** | Class IIa | N/A | CE 670390; NB 2797 |
| **MULTIFUNCTIONAL HEALING ABUTMENT - 78996338ACS004VF** | Class IIb excluding Class IIb implantable non-WET | N/A | CE 670390; NB 2797 |
| **BURNOUT CoCr COPING - 78996338ACS005VH** | Class IIb excluding Class IIb implantable non-WET | N/A | CE 670390; NB 2797 |
| **ARCSYS ABUTMENT - 78996338ACS006VK** | Class IIb excluding Class IIb implantable non-WET | N/A | CE 670390; NB 2797 |
| **MULTIFUNCTIONAL IMPRESSION CAP - 78996338ACS007VM** | Class IIb excluding Class IIb implantable non-WET | N/A | CE 670390; NB 2797 |

**Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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 |
|---|---|
| 2023/05/26 | Initial issue |