Argon Medical Productions & Vertriebs GmbH & Co. KG
Franz-Kirsten-Str.1
Bingen
55411
Germany

22nd of March 2024

Notified Body Confirmation Letter

Reference: EU2023-607/818152

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:

Argon Medical Productions & Vertriebs GmbH & Co. KG
Franz-Kirsten-Str.1
Bingen
55411
Germany

SRN Number: DE-MF-000012472

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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
K3Pro Sure / S_Line Implants	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
K3Pro Rapid / R_Line Implants	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
K3Pro SHORT Implants	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
K3Pro Compress / C_Line Implants	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Standard Abutments - PreForm (EAK) - Anatomic (AA) - Emergenz (EAZ) - Orthodontic Abutment (GIA)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Titanium bases - Klebe/Scan (KSA) - FlexiBase (FB/CG.V/CG.FB) - ClouBase (CG.C) - Cerec (CS) - Basis Abutment (GAT)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Multi-units - RapidFix (VBA) - Multibase (MB) - STEG-Basis (SB/SBA)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Locator - Locator (FLA)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227

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
- DockLocs (DLA) - Kugelkopf (KKA)			*expiry date* 2024-05-26*;* NB2797
Individual machinable - Premills (CAD/PM) - FreeForm (FF) - Cobalt-Chrome (CCA)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Temporary Abutments (non-active plastic and metal) - Gingivaformer (TA) - Provisiorische Aufbauten (PA) - Rescue (RA) - Temporäre Aufbauten (TPA) - Bone Profile Screw (BPS) - Healing/Sealing Screw (IKAS)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Implant-/Abutment Screws - Abutments screw (AS) - Abutments screw (ETS) - Cover Screw (VS) - Cutable healing plug (PK) - Healing plug (TPE) - XP-Screw (TBS)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
K3Pro Caps - O-Ring Cap KKA (KK_GK) - Peek Cap KSA (KSA_PT) - MB 4000LK.TI - MB 4000PK_PK - MB 4000PM_TI - MB 4000TB_TI - Gingiva Cap MB (MB.GK) - Locator Cap MB (MB.LK) - Cover Cap MB (MB.VK) - VBA50000GV	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797

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
- VBA50000GV.PK - VBA50000PKK.ELITOR - VBA50000PKK.HSLA - VBA50000PKK.PK - VBA50000PKK.T - ParaKonus Caps VBA (VBA.PKK) - Sealing Cap VBA (VBA_VK) - Locator Cap VBA (VBA_LK) - Glue Cap VBA (VBA_KK)			
K3Pro Sleeves - Titanium Sleeve MB (MB.TH) - Glue Sleeve MB (MB.KH) - Sleeve FLA (FLA_A60015/3)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
K3Pro Pins - Sealing Pin RA (RA_VS)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
K3Pro Matrits - Para Konus Matrizen VBA (VBA.PKM) - Matrizen FLA (FLM) - Matrizen DLA (DLR_10)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
K3Pro Rings - O-Ring KKA (KK_OR) - Insert FLA (FLR) - Screw Ring EAZ (EAZ_SK) - Insert DLR grey (DLR_01) - Insert DLR blue (DLR_02) - Insert DLR pink (DLR_03) - Insert DLR clear (DLR_04) - Insert DLR red (DLR_05)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797

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- Insert DLR orange (DLR_06) - Insert DLR green (DLR_07) - Insert DLR black (DLR_08) - Distance sleeve DLR (DLR_012)			
Accessory screws - Cover Screw (VS) - Screw for SBA (SBA.HS) - Screw MB (MB.S) - Screw FLA (FLA_AS) - Retention Screw (HSAMII) - Fixation Screw (HSVBA) - Screw EAZ (EAZ_TS)	*Class IIb - Implantable - WET*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Pilot Drill KB.STLD (Lance Drill) KB_SLB.01 (Lance Drill narrow) KB1.9K (Round Bur) KB (Pilot Drill) KPB (Pilot Drill Titanium) OSB_XXXXXX.DK (OsteoScrew Triangular Drill) OSB_XXXXXX.S (OsteoScrew Spiral Drill) SPB (Spiral Drill)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Implant Drill-surgical steel KKB (Implant Drill conical) KUB (Implant Drill universal) KZB (Implant Drill cylindrical)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Implant Drill-Titanium KRB (Implant Drill conical) KSB (Implant Drill cylindrical) RS_EB (Extension Drill) DSB (Densification Drill)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Rapid Surgery-Pilot Drill RS_PB (Pilot Drill)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227

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			expiry date 2024-05-26; NB2797
Rapid Surgery-Cortical Drill RS_KB (Cortical Drill)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Rapid Surgery-Final Drill RS_B (Implant Drill)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Screwdriver WSE_SK1.2 (Hex Screwdriver)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Implant Inserter WSEI (Implant Inserter) RSIE (RS Implant Inserter) FLWE (Finder/Locator Inserter) KKEI (O-Ring Inserter) VBA_EI (RapidFix Inserter)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Removal tool AAA.MB (MB Removal tool) AAA.WS (Abutment removal tool)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Rescue tools RSAB (Drill to counterbore screw) RSB (Rescue Drill for Screw)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Extensions KBV (K3Pro Drill Extension)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797
Adapter BH (Drill Sleeve) RS_BH (RS Drill Sleeve) RS_ARH (RS Adaptor Reduction) RS_BRR (RS Drill Reduction)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26; NB2797

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Sulcus Reamer SF.WSA (K3Pro Sulcus Reamer)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Uncovering Instruments FL_VSK (for Cover Screws)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Tap Instruments RS_GS (RS Tap) GS (Implant Tap K3Pro)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Bone Condenser KK (K3Pro Bone Condenser)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Sinker K (Implant Sinker K3Pro)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Trephine Bur TF (Osteo Trephine Bur) TF_RS (RS Trephine Bur)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Starter Bur/Levelling Bur RS_PF (RS Levelling Bur) RS_K (RS Starter Bur)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797
Gingiva Punch GS_RS (RS Gingiva Punch)	*Class IIa*	Not Applicable	*MDD Certificate* CE 642227 *expiry date* 2024-05-26*;* NB2797

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
2024/03/22	Initial issue