



CERTIFICATE

*This certifies that the Quality management system for medical devices
of company*

LASAK s.r.o.

Seat: Českobrodská 1047/46, Hloubětín, 190 00 Praha 9, Czech Republic

Site: Jiráskova 601, 295 01 Mnichovo Hradiště, Czech Republic



*has been assessed by 3EC International
and found to be in conformance with the following standard:*

EN ISO 13485:2016

for the following scope:

**DESIGN AND DEVELOPMENT, PRODUCTION, SALES, DISTRIBUTION AND SERVICE
OF NON-ACTIVE IMPLANTABLE MEDICAL DEVICES, COMPONENTS AND SUBASSEMBLIES.
DENTAL IMPLANT SYSTEMS INCLUDING ENDOSTEAL IMPLANTS, ABUTMENTS, CROWNS,
BRIDGES, DENTAL KITS, OTHER ASSOCIATED PROSTHETIC AND IMPRESSION COMPONENTS,
INSTRUMENTS AND ACCESSORIES (BioniQ, IMPLADENT).
CUSTOM-MADE DEVICES FOR USE IN ORAL AND MAXILLOFACIAL SURGERY AND IMPLANTOLOGY
SPINAL IMPLANTS AND ASSOCIATED INSTRUMENTS AND ACCESSORIES (IMPLASPIN).
SYNTHETIC RESORBABLE AND NON-RESORBABLE MATERIALS FOR BONE REGENERATION
(PORESORB-TCP, OssaBase-HA).
CUSTOM-MADE MEDICAL DEVICES CRANIAL IMPLANTS (Cranio-Oss).**

Certificate No.: M-0557/23

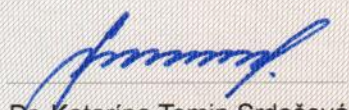
Date of issuance: October 27th, 2023

Original date of approval: October 27th, 2023

This certificate is valid from **October 27th, 2023** to **October 26th, 2026** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic




Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices covered by EA MLA and IAF MLA.

LASAK s.r.o.
Českobrodská 1047/46
Hloubětín
190 00 Praha 9
Czech Republic

Attn. Ing. Jakub Strnad Ph.D. / director

Our reference
MIT/2024/P085

Contact person
Michal Tomin / +421 915 366 774

BRATISLAVA
24.5.2024

Subject: Notified Body Confirmation Letter

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 amended as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **3EC International a.s.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2265 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:

LASAK s.r.o.
Českobrodská 1047/46
Hloubětín
190 00 Praha 9
Czech Republic

SRN Number (if available): CZ-MF-000031907

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices 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 the Notified Body,



3EC International a.s. 
Hraničná 18, 821 05 Bratislava
Slovak Republic
ID No.: 36 789 003
VAT No.: SK2022390073

Katarína Tomin Srdošová, PhD.

Director of NB2265

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
Trade name: Cranio-Oss	Class III implantable custom-made device	N/A	N/A - Device did not require a Notified Body certificate under Directives
Temporary implant Trade name: ProImplant, ProImplant-Final Drill Models: 6102.3 ProImplant D2.1/L10 7102.3 ProImplant D2.1/L14 5102.3 ProImplant D2.1/L7 01314.3 ProImplant - Final Drill D2.1/d1.5	Class IIa Class IIb excluding Class IIb implantable non-WET	Dental implant system IMPLADENT-dental implants was substituted to ProImplant, ProImplant-Final Drill	MED 190037 MED 190043 NB1014
Resorbable ceramics based on β -tricalcium phosphate Trade name: PORESORB -TCP Models: 32:2 PORESORB-TCP 0.16-0.3mm/0.5ml/0.5g 31:2 PORESORB-TCP 0.16-0.3mm/1.0ml/1.0g 13:2 PORESORB-TCP 0.3-0.6mm/0.5ml/0.5g 11:2 PORESORB-TCP 0.3-0.6mm/1.0ml/1.0g 23:2 PORESORB-TCP 0.6-1.0mm/0.5ml/0.5g 21:2 PORESORB-TCP 0.6-1.0mm/1.0ml/1.0g	Class III	Synthetic resorbable material for bone regeneration PORESORB-TCP was substituted to PORESORB-TCP in application, Granules were substituted from 0.16mm to 6.0 mm	MED 200012 MED 200011 NB1014

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia IČO: 36 789 003 IČ DPH: SK2022390073
Tel/Fax: 00421 (0)2 5831 8343 / - 45 e-mail: info@3ec.sk web: http://www.3ec.sk

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22:2 PORESORB-TCP 0.6- 1.0mm/2.0ml/2.0g 122:2 PORESORB-TCP 0.6- 1.0mm/2.0ml/2.0g 24:2 PORESORB-TCP 0.6- 1.0mm/4.0ml/4.0g 141:2 PORESORB-TCP 1.0- 2.0mm/1.2ml/1.0g 41:2 PORESORB-TCP 1.0- 2.0mm/1.2ml/1.0g 42:2 PORESORB-TCP 1.0- 2.0mm/2.4ml/2.0g 142:2 PORESORB-TCP 1.0- 2.0mm/2.4ml/2.0g 144:2 PORESORB-TCP 1.0- 2.0mm/4.8ml/4.0g 44:2 PORESORB-TCP 1.0- 2.0mm/4.8ml/4.0g 148:2 PORESORB-TCP 1.0- 2.0mm/9.6ml/8.0g 48:2 PORESORB-TCP 1.0- 2.0mm/9.6ml/8.0g 164:2 PORESORB-TCP 2.0- 3.0mm/4.8ml/4.0g 168:2 PORESORB-TCP 2.0- 3.0mm/9.6ml/8.0g 184:2 PORESORB-TCP 3.0- 6.0mm/6.0ml/4.0g 186:2 PORESORB-TCP 3.0- 6.0mm/9.0ml/6.0g			
Intervertebral disc replacement made of PEEK-OPTIMA™ HA Enhanced Trade name: IMPLASPIN Models: 7007.10 IMPLASPIN lumbar PEEK/H10/L21/0° 7008.10 IMPLASPIN lumbar PEEK/H10/L25/0° 7007.12 IMPLASPIN lumbar PEEK/H12/L21/0° 7008.12 IMPLASPIN lumbar PEEK/H12/L25/0° 7007.08 IMPLASPIN lumbar PEEK/H8/L21/0° 7008.08 IMPLASPIN lumbar PEEK/H8/L25/0° 7006.05 IMPLASPIN cervical PEEK/H5/W14/L12/3° 7005.05 IMPLASPIN cervical PEEK/H5/W17/L14/3° 7006.06 IMPLASPIN cervical PEEK/H6/W14/L12/3° 7005.06 IMPLASPIN cervical PEEK/H6/W17/L14/3° 7006.07 IMPLASPIN cervical PEEK/H7/W14/L12/3° 7005.07 IMPLASPIN cervical PEEK/H7/W17/L14/3° 7006.08 IMPLASPIN cervical PEEK/H8/W14/L12/3° 7005.08 IMPLASPIN cervical PEEK/H8/W17/L14/3°	Class III	IMPLASPIN in application on certificate Spinal implants class IIb, see enclosure Spinal implant IMPLASPIN-PEEK	MED 200010 NB1014

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Bioceramics based on hydroxyapatite Ca₁₀(PO₄)₆(OH)₂ Trade name: OssaBase-HA Models: 15:6 OssaBase-HA 0.3-0.6mm/0.5ml/0.25g 13:6 OssaBase-HA 0.3-0.6mm/1ml/0.5g 11:6 OssaBase-HA 0.3-0.6mm/2ml/1g 25:6 OssaBase-HA 0.6-1mm/0.5ml/0.25g 23:6 OssaBase-HA 0.6-1mm/1ml/0.5g 21:6 OssaBase-HA 0.6-1mm/2ml/1g 44:6 OssaBase-HA 1-2mm/10ml/4g 144:6 OssaBase-HA 1-2mm/10ml/4g 43:6 OssaBase-HA 1-2mm/1ml/0.4g 143:6 OssaBase-HA 1-2mm/1ml/0.4g 41:6 OssaBase-HA 1-2mm/2.5ml/1g 141:6 OssaBase-HA 1-2mm/2.5ml/1g 40:6 OssaBase-HA 1-2mm/2ml/0.8g 140:6 OssaBase-HA 1-2mm/2ml/0.8g 42:6 OssaBase-HA 1-2mm/5.0ml/2g 142:6 OssaBase-HA 1-2mm/5.0ml/2g	Class III	Synthetic material for bone regeneration OssaBase-HA was substituted to OssaBase-HA Granules were substituted from 0.3 to 6.0 mm	MED 200024 NB1014
BioniQ Dental Implants Models: BioniQ implant Plus – straight 2026.10 BioniQ implant Plus – straight 2026.12 BioniQ implant Plus – straight 2026.14 BioniQ implant Plus – straight 2027.10 BioniQ implant Plus – straight 2027.12 BioniQ implant Plus – straight 2027.14 BioniQ implant Plus – straight 2027.08 BioniQ implant Plus – straight 2028.10 BioniQ implant Plus – straight 2028.12 BioniQ implant Plus – straight 2028.14 BioniQ implant Plus – straight 2028.06 BioniQ implant Plus – straight 2028.08 BioniQ implant Plus – straight 2029.08 BioniQ implant Plus – straight 2029.10 BioniQ implant Plus – straight 2029.12 BioniQ implant Plus – straight 2029.14 BioniQ implant Plus – straight 2029.06 BioniQ implant – straight 2003.10 BioniQ implant – straight 2003.12 BioniQ implant – straight 2003.14	Class IIb excluding Class IIb implantable non-WET	N/A	MED 190037 NB1014

BioniQ implant – straight 2003.16 BioniQ implant – straight 2006.10 BioniQ implant – straight 2006.12 BioniQ implant – straight 2006.14 BioniQ implant – straight 2006.16 BioniQ implant – straight 2006.08 BioniQ implant – straight 2009.10 BioniQ implant – straight 2009.12 BioniQ implant – straight 2009.14 BioniQ implant – straight 2009.16 BioniQ implant – straight 2009.06 BioniQ implant – straight 2009.08 BioniQ implant – straight 2017.10 BioniQ implant – straight 2017.12 BioniQ implant – straight 2017.14 BioniQ implant – straight 2017.16 BioniQ implant – straight 2017.06 BioniQ implant – straight 2017.08 BioniQ implant – tapered 2012.10 BioniQ implant – tapered 2012.12 BioniQ implant – tapered 2012.14 BioniQ implant – tapered 2012.16 BioniQ implant – tapered 2012.08 BioniQ implant – tapered 2020.10 BioniQ implant – tapered 2020.12 BioniQ implant – tapered 2020.14 BioniQ implant – tapered 2020.16 BioniQ implant – tapered 2020.08			
BioniQ Instruments Models: 2458.00 Gingival height gauge BioniQ 2410.00 Guide wrench BioniQ 2528.00 Insertion wrench BioniQ for guided surgery (GS) 2403.00 Insertion wrench BioniQ – long 2402.00 Insertion wrench BioniQ – extra short 2423.00 Depth gauge S2.9 2428.00 Depth gauge S3.5 2434.00 Depth gauge S4.0/T4.0 2440.00 Depth gauge S5.0/T5.0 2459.00 Unigrip BioniQ 2417.00 Paralleling pin 2526.22 Guided fixation pin – horizontal, d1.3/L30/L22 (GS) 2526.00 Guided fixation pin – horizontal, d1.3/L25/L17 (GS) 2408.00 Ratchet BioniQ (Im)	Class I devices that qualify as re-usable surgical instruments Class I devices with a measuring function	N/A	MED 200017 NB1014
BioniQ Instruments Models: 2521.00 Trephine for guided surgery – d3.35 (GS) 2522.00 Trephine for guided surgery – d4.65 (GS) 2414.3 Trephine d4.5 5214.3 Trephine d6.0 2442.00 Explantation drill S5.0/T5.0 2436.00 Explantation drill S4.0/T4.0 2429.00 Explantation drill S3.5	Class IIa	N/A	MED 190043 NB1014

2424.00 Explantation drill S2.9			
2527.00 Guided drill for pin, d1.3 (GS)			
2495.00 Guided drill S5.0 – long (GS)			
2494.00 Guided drill S5.0 – medium (GS)			
2493.00 Guided drill S5.0 – short (GS)			
2492.00 Guided drill S4.0 – long (GS)			
2491.00 Guided drill S4.0 – medium (GS)			
2490.00 Guided drill S4.0 – short (GS)			
2489.00 Guided drill S3.5 – long (GS)			
2488.00 Guided drill S3.5 – medium (GS)			
2487.00 Guided drill S3.5 – short (GS)			
2486.00 Guided drill S2.9 – medium (GS)			
2485.00 Guided drill S2.9 – long (GS)			
2484.00 Guided drill S2.9 – short (GS)			
2470.00 Final drill S5.0 – short, drill stop compatible (DS/C)			
2469.00 Final drill S4.0 – short, drill stop compatible (DS/C)			
2468.00 Final drill S3.5 – short, drill stop compatible (DS/C)			
2467.00 Final drill S2.9 – short, drill stop compatible (DS/C)			
2464.00 Final drill S5.0 – long, drill stop compatible (DS/C)			
2463.00 Final drill S4.0 – long, drill stop compatible (DS/C)			
2462.00 Final drill S3.5 – long, drill stop compatible (DS/C)			
2461.00 Final drill S2.9 – long, drill stop compatible (DS/C)			
2451.00 Final drill S5.0 – short			
2449.00 Final drill S4.0 – short			
2448.00 Final drill S3.5 – short			
2447.00 Final drill S2.9 – short			
2446.00 Pilot drill d1.5			
2437.00 Final drill S5.0			
2430.00 Final drill S4.0			
2425.00 Final drill S3.5			
2420.00 Final drill S2.9			
2502.00 Guided drill T5.0 – long (GS)			
2501.00 Guided drill T5.0 – medium (GS)			
2500.00 Guided drill T5.0 – short (GS)			
2499.00 Guided drill T4.0 – long (GS)			
2498.00 Guided drill T4.0 – medium (GS)			
2497.00 Guided drill T4.0 – short (GS)			
2472.00 Final drill T5.0 – short, drill stop compatible (DS/C)			
2471.00 Final drill T4.0 – short, drill stop compatible (DS/C)			

2466.00 Final drill T5.0 – long, drill stop compatible (DS/C) 2465.00 Final drill T4.0 – long, drill stop compatible (DS/C) 2452.00 Final drill T5.0 – short 2450.00 Final drill T4.0 – short 2441.00 Final drill T5.0 2435.00 Final drill T4.0 2510.00 Countersink for guided surgery S5.0/T5.0 (GS) 2508.00 Countersink for guided surgery S4.0/T4.0 (GS) 2506.00 Countersink for guided surgery S3.5 (GS) 2504.00 Countersink for guided surgery S2.9 (GS) 2439.00 Countersink S5.0/T5.0 2433.00 Countersink S4.0/T4.0 2427.00 Countersink S3.5 2422.00 Countersink S2.9 2509.00 Threadformer for guided surgery S5.0/T5.0 (GS) 2507.00 Threadformer for guided surgery S4.0/T4.0 (GS) 2505.00 Threadformer for guided surgery S3.5 (GS) 2503.00 Threadformer for guided surgery S2.9 (GS) 2438.00 Threadformer S5.0/T5.0 2431.00 Threadformer S4.0/T4.0 2426.00 Threadformer S3.5 2421.00 Threadformer S2.9 2445.00 Drill extension ISO 2411.00 Drill extension ISO 2534.36 Screwdriver AN – mechanical, long - AN/ISO/tx1.9/L36 2534.28 Screwdriver AN – mechanical, short - AN/ISO/tx1.9/L28 2534.21 Screwdriver AN - mechanical, extra short - AN/ISO/tx1.9/L21 2413.21 Screwdriver – mechanical, long hex1.25/ISO/L21 2413.11 Screwdriver – mechanical, short hex1.25/ISO/L11 2444.00 Insertion wrench BioniQ – mechanical, long hex2.5/ISO/L18 2412.00 Insertion wrench BioniQ – mechanical, short hex2.5/ISO/L4 2531.00 Direct Driver QR – mechanical (GS)QR/ISO/L18 2530.00 Direct Driver QN – mechanical (GS)QN/ISO/L18 2457.18 Direct Driver QR – mechanical, long - QR/ISO/L18 2457.07 Direct Driver QR – mechanical, short - QR/ISO/L7 2454.18 Direct Driver QN – mechanical, long -QN/ISO/L18 2512.00 Cover Screw Mill QR/3.5/4.0/5.0 2511.00 Cover Screw Mill - QN/2.9			
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2443.00 Roundburr d1.8			
BioniQ Prosthetics Components Models: 2229.00 Fixing screw AN, BioniQ QR/AN/tx1.9 2228.00 Fixing screw AN, BioniQ QN/AN/tx1.9 2191.00 Fixing screw, BioniQ QN/hex1.25 2161.30 PLS BioniQ – fixing screw, slot QR/B 2103.00 Fixing screw, BioniQ - QR/hex1.25 2120.00 Screw-On healing cap d4.6 2168.00 Healing cap STANDARD – narrow, set of 2 pcs. - d4.0 2118.00 Healing cap STANDARD – wide, set of 2 pcs. - d5.0 2167.06 Gingiva former – wide-QN/d4.6/L6 2167.04 Gingiva former – wide-QN/d4.6/L4 2167.02 Gingiva former – wide-QN/d4.6/L2 2166.06 Gingiva former – narrow-QN/d3.9/L6 2166.04 Gingiva former – narrow-QN/d3.9/L4 2166.02 Gingiva former – narrow-QN/d3.9/L2 2116.06 Gingiva former – bridge-QR/B/d4.9/L6 2116.04 Gingiva former – bridge-QR/B/d4.9/L4 2116.02 Gingiva former – bridge-QR/B/d4.9/L2 2111.06 Gingiva former – extra wide-QR/d7.0/L6 2111.04 Gingiva former – extra wide-QR/d7.0/L4 2110.06 Gingiva former wide QR/d5.2/L6 2110.04 Gingiva former – wide QR/d5.2/L4 2110.02 Gingiva former – wide QR/d5.2/L2 2109.06 Gingiva former – narrow QR/d4.2/L6 2109.04 Gingiva former – narrow QR/d4.2/L4 2109.02 Gingiva former – narrow QR/d4.2/L2 2237.00 Screw-On bridge screw AN AN/tx1.9 2106.00 Screw-On bridge screw hex1.25 BioniQ Prosthetics Components Models:	Class IIa Class IIb excluding Class IIb implantable non-WET	N/A	MED 190043 NB1014

2207.05 Base BioCam, BioniQ, Screw-On, set of 5 pcs.- d4.6/d5.0/h5.0/L0.4 2207.00 Base BioCam, BioniQ, Screw-On - d4.6/d5.0/h5.0/L0.4 2164.00 Cover screw, basic - QN 2107.00 Cover screw, basic - QR 2198.00 Ti base CEREC QN/inCoris ZI meso S 2189.20 BioCam abutment, BioniQ, non-indexed- QN/NI/d3.7/L2.0 2189.00 BioCam abutment, BioniQ, non-indexed- QN/NI/d3.7/L0.8 2186.20 BioCam abutment, BioniQ, non-indexed- QR/NI/d3.7/L2.0 2186.00 BioCam abutment, BioniQ, non-indexed- QR/NI/d3.7/L0.8 2183.00 Ti base CEREC QR/inCoris ZI meso L 2181.20 BioCam abutment, BioniQ, indexed QN/d3.7/L2.0 2181.00 BioCam abutment, BioniQ, indexed QN/d3.7/L0.8 2159.20 BioCam abutment, BioniQ, indexed QR/d3.7/L2.0 2159.00 BioCam abutment, BioniQ, indexed QR/d3.7/L0.8 2158.20 BioCam abutment, BioniQ, bridge QR/B/d3.7/L2.0 2158.00 BioCam abutment, BioniQ, bridge QR/B/d3.7/L0.4 2188.00 Cast-On abutment, BioniQ, non-indexed QN/NI/d3.8 2185.00 Cast-On abutment, BioniQ, non-indexed QR/NI/d3.9 2179.00 Cast-On abutment, BioniQ, indexed QN/d3.8 2154.00 Cast-On abutment, BioniQ, indexed QR/d3.9 2153.00 Cast-On abutment, BioniQ, bridge QR/B/d3.9 2178.05 Screw-On abutment –angled QN/d4.6/20°/L5 2178.04 Screw-On abutment –angled QN/d4.6/20°/L4 2178.03 Screw-On abutment –angled QN/d4.6/20°/L3 2177.04 Screw-On abutment straight QN/d4.6/L4 2177.03 Screw-On abutment straight QN/d4.6/L3 2177.02 Screw-On abutment straight QN/d4.6/L2 2177.01 Screw-On abutment straight QN/d4.6/L1 2171.30 Esthetic abutment – angled, narrow QN/d3.8/15°/L3.0 2171.15 Esthetic abutment – angled, narrow QN/d3.8/15°/L1.5 2171.07 Esthetic abutment – angled, narrow QN/d3.8/15°/L0.7			
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2170.30 Esthetic abutment – straight, narrow QN/d3.8/L3.0 2170.15 Esthetic abutment – straight, narrow QN/d3.8/L1.5 2170.07 Esthetic abutment – straight, narrow QN/d3.8/L0.7 2169.04 STANDARD abutment - narrow, straight QN/d4.0/L4 2169.03 STANDARD abutment – narrow, straight QN/d4.0/L3 2169.02 STANDARD abutment – narrow, straight QN/d4.0/L2 2169.01 STANDARD abutment – narrow, straight QN/d4.0/L1 2150.05 Screw-On abutment – angled QR/d4.6/30°/L5 2150.04 Screw-On abutment – angled QR/d4.6/30°/L4 2149.05 Screw-On abutment – angled QR/d4.6/20°/L5 2149.04 Screw-On abutment – angled QR/d4.6/20°/L4 2149.03 Screw-On abutment – angled QR/d4.6/20°/L3 2148.04 Screw-On abutment – straight QR/d4.6/L4 2148.03 Screw-On abutment – straight QR/d4.6/L3 2148.02 Screw-On abutment – straight QR/d4.6/L2 2148.01 Screw-On abutment – straight QR/d4.6/L1 2143.30 Esthetic abutment – angled, wide - QR/d5.2/25°/L3.0 2143.15 Esthetic abutment – angled, wide - QR/d5.2/25°/L1.5 2143.07 Esthetic abutment – angled, wide - QR/d5.2/25°/L0.7 2141.30 Esthetic abutment – angled, wide - QR/d5.2/15°/L3.0 2141.15 Esthetic abutment – angled, wide - QR/d5.2/15°/L1.5 2141.07 Esthetic abutment – angled, wide - QR/d5.2/15°/L0.7 2140.30 Esthetic abutment – straight, wide - QR/d5.2/L3.0 2140.15 Esthetic abutment – straight, wide - QR/d5.2/L1.5 2140.07 Esthetic abutment – straight, wide - QR/d5.2/L0.7 2139.30 Esthetic abutment – angled, narrow QR/d3.9/25°/L3.0 2139.15 Esthetic abutment – angled, narrow QR/d3.9/25°/L1.5 2139.07 Esthetic abutment – angled, narrow QR/d3.9/25°/L0.7 2138.30 Esthetic abutment – angled, narrow QR/d3.9/15°/L3.0 2138.15 Esthetic abutment – angled, narrow QR/d3.9/15°/L1.5 2138.07 Esthetic abutment – angled, narrow QR/d3.9/15°/L0.7 2137.30 Esthetic abutment – straight, narrow QR/d3.9/L3.0			
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2137.15 Esthetic abutment – straight, narrow QR/d3.9/L1.5 2137.07 Esthetic abutment – straight, narrow QR/d3.9/L0.7 2133.04 STANDARD abutment – wide, straight - QR/d5.0/L4 2133.03 STANDARD abutment – wide, straight - QR/d5.0/L3 2133.02 STANDARD abutment – wide, straight - QR/d5.0/L2 2133.01 STANDARD abutment – wide, straight - QR/d5.0/L1 2129.04 STANDARD abutment – narrow, straight - QR/d4.0/L4 2129.03 STANDARD abutment – narrow, straight - QR/d4.0/L3 2129.02 STANDARD abutment – narrow, straight - QR/d4.0/L2 2129.01 STANDARD abutment – narrow, straight - QR/d4.0/L1 2871.00 Screw-On burn-out coping with CoCr base - d4.6 2161.20 PLS BioniQ – bridge support, CoCr - QR/B 2161.10 PLS BioniQ – bridge support, Ti - QR/B 2231.05 Temporary cap Screw-On, set of 5 pcs. - d4.6 2231.00 Temporary cap Screw-On-d4.6 2200.03 Temporary abutment – non-indexed QR/NI/d4.0/L3 2200.01 Temporary abutment – non-indexed QR/NI/d4.0/L1 2128.03 Temporary abutment bridge QR/B/d4.0/L3 2128.01 Temporary abutment bridge QR/B/d4.0/L1 2127.03 Temporary abutment - indexed QR/d4.0/L3 2127.01 Temporary abutment – indexed QR/d4.0/L1 2126.03 Temporary abutment – non-indexed QN/NI/d3.8/L3 2126.01 Temporary abutment – non-indexed QN/NI/d3.8/L1 2125.03 Temporary abutment – indexed QN/d3.8/L3 2125.01 Temporary abutment – indexed QN/d3.8/L1 2235.35 Uni-Base, BioniQ, non-indexed, wide - QR/NI/d4.5/h3.5/L3.5 2235.25 Uni-Base, BioniQ, non-indexed, wide- QR/NI/d4.5/h3.5/L2.5 2235.15 Uni-Base, BioniQ, non-indexed, wide - QR/NI/d4.5/h3.5/L1.5 2235.07 Uni-Base, BioniQ, non-indexed, wide - QR/NI/d4.5/h3.5/L0.7			
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2234.35 Uni-Base, BioniQ, bridge, wide- QR/B/d4.5/h3.5/L3.5 2234.25 Uni-Base, BioniQ, bridge, wide - QR/B/d4.5/h3.5/L2.5 2234.15 Uni-Base, BioniQ, bridge, wide - QR/B/d4.5/h3.5/L1.5 2234.07 Uni-Base, BioniQ, bridge, wide - QR/B/d4.5/h3.5/L0.7 2230.35 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h3.5/L3.5 2230.25 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h3.5/L2.5 2230.15 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h3.5/L1.5 2230.07 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h3.5/L0.7 2227.35 Uni-Base AN, BioniQ, non- indexed, wide- QR/NI/AN/d4.5/h5.5/L3.5 2227.25 Uni-Base AN, BioniQ, non- indexed, wide - QR/NI/AN/d4.5/h5.5/L2.5 2227.15 Uni-Base AN, BioniQ, non- indexed, wide - QR/NI/AN/d4.5/h5.5/L1.5 2227.07 Uni-Base AN, BioniQ, non- indexed, wide- QR/NI/AN/d4.5/h5.5/L0.7 2226.35 Uni-Base AN, BioniQ, bridge, wide-QR/B/AN/d4.5/h5.5/L3.5 2226.25 Uni-Base AN, BioniQ, bridge, wide-QR/B/AN/d4.5/h5.5/L2.5 2226.15 Uni-Base AN, BioniQ, bridge, wide-QR/B/AN/d4.5/h5.5/L1.5 2226.07 Uni-Base AN, BioniQ, bridge, wide-QR/B/AN/d4.5/h5.5/L0.7 2225.35 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h8.0/L3.5 2225.25 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h8.0/L2.5 2225.15 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h8.0/L1.5 2225.07 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h8.0/L0.7 2221.35 Uni-Base, BioniQ, bridge, wide - QR/B/d4.5/h5.5/L3.5 2221.25 Uni-Base, BioniQ, bridge, wide - QR/B/d4.5/h5.5/L2.5 2221.15 Uni-Base, BioniQ, bridge, wide - QR/B/d4.5/h5.5/L1.5 2221.07 Uni-Base, BioniQ, bridge, wide - QR/B/d4.5/h5.5/L0.7 2220.35 Uni-Base, BioniQ, non- indexed, wide - QR/NI/d4.5/h5.5/L3.5 2220.25 Uni-Base, BioniQ, non- indexed, wide - QR/NI/d4.5/h5.5/L2.5 2220.15 Uni-Base, BioniQ, non- indexed, wide - QR/NI/d4.5/h5.5/L1.5 2220.07 Uni-Base, BioniQ, non- indexed, wide - QR/NI/d4.5/h5.5/L0.7			
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2219.35 Uni-Base AN, BioniQ, indexed, wide - QR/AN/d4.5/h5.5/L3.5 2219.25 Uni-Base AN, BioniQ, indexed, wide - QR/AN/d4.5/h5.5/L2.5 2219.15 Uni-Base AN, BioniQ, indexed, wide - QR/AN/d4.5/h5.5/L1.5 2219.07 Uni-Base AN, BioniQ, indexed, wide - QR/AN/d4.5/h5.5/L0.7 2218.35 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h5.5/L3.5 2218.25 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h5.5/L2.5 2218.15 Uni-Base, BioniQ, indexed, wide- QR/d4.5/h5.5/L1.5 2218.07 Uni-Base, BioniQ, indexed, wide - QR/d4.5/h5.5/L0.7 2217.35 Uni-Base, BioniQ, non-indexed, narrow QR/NI/d3.8/h5.5/L3.5 2217.25 Uni-Base, BioniQ, non-indexed, narrow QR/NI/d3.8/h5.5/L2.5 2217.15 Uni-Base, BioniQ, non-indexed, narrow QR/NI/d3.8/h5.5/L1.5 2217.07 Uni-Base, BioniQ, non-indexed, narrow QR/NI/d3.8/h5.5/L0.7 2216.35 Uni-Base, BioniQ, indexed, narrow QR/d3.8/h5.5/L3.5 2216.25 Uni-Base, BioniQ, indexed, narrow QR/d3.8/h5.5/L2.5 2216.15 Uni-Base, BioniQ, indexed, narrow QR/d3.8/h5.5/L1.5 2216.07 Uni-Base, BioniQ, indexed, narrow QR/d3.8/h5.5/L0.7 2215.35 Uni-Base AN, BioniQ, non-indexed, wide-QN/NI/AN/d4.5/h5.5/L3.5 2215.25 Uni-Base AN, BioniQ, non-indexed, wide-QN/NI/AN/d4.5/h5.5/L2.5 2215.15 Uni-Base AN, BioniQ, non-indexed, wide-QN/NI/AN/d4.5/h5.5/L1.5 2215.07 Uni-Base AN, BioniQ, non-indexed, wide-QN/NI/AN/d4.5/h5.5/L0.7 2213.35 Uni-Base, BioniQ, non-indexed, wide - QN/NI/d4.5/h5.5/L3.5 2213.25 Uni-Base, BioniQ, non-indexed, wide - QN/NI/d4.5/h5.5/L2.5 2213.15 Uni-Base, BioniQ, non-indexed, wide - QN/NI/d4.5/h5.5/L1.5 2213.07 Uni-Base, BioniQ, non-indexed, wide - QN/NI/d4.5/h5.5/L0.7 2211.35 Uni-Base AN, BioniQ, indexed, wide-QN/AN/d4.5/h5.5/L3.5 2211.25 Uni-Base AN, BioniQ, indexed, wide-QN/AN/d4.5/h5.5/L2.5 2211.15 Uni-Base AN, BioniQ, indexed, wide-QN/AN/d4.5/h5.5/L1.5			
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2211.07 Uni-Base AN, BioniQ, indexed, wide-QN/AN/d4.5/h5.5/L0.7 2210.35 Uni-Base, BioniQ, indexed, wide - QN/d4.5/h5.5/L3.5 2210.25 Uni-Base, BioniQ, indexed, wide- QN/d4.5/h5.5/L2.5 2210.15 Uni-Base, BioniQ, indexed, wide- QN/d4.5/h5.5/L1.5 2210.07 Uni-Base, BioniQ, indexed, wide - QN/d4.5/h5.5/L0.7 2209.35 Uni-Base, BioniQ, non-indexed, narrow QN/NI/d3.8/h5.5/L3.5 2209.25 Uni-Base, BioniQ, non-indexed, narrow QN/NI/d3.8/h5.5/L2.5 2209.15 Uni-Base, BioniQ, non-indexed, narrow QN/NI/d3.8/h5.5/L1.5 2209.07 Uni-Base, BioniQ, non-indexed, narrow QN/NI/d3.8/h5.5/L0.7 2208.35 Uni-Base, BioniQ, indexed, narrow QN/d3.8/h5.5/L3.5 2208.25 Uni-Base, BioniQ, indexed, narrow QN/d3.8/h5.5/L2.5 2208.15 Uni-Base, BioniQ, indexed, narrow QN/d3.8/h5.5/L1.5 2208.07 Uni-Base, BioniQ, indexed, narrow QN/d3.8/h5.5/L0.7 2251.00 Premill abutment, BioniQ, AG – CoCr - QN/d12 2250.00 Premill abutment, BioniQ, AG – CoCr - QR/d12 2249.00 Premill abutment, BioniQ, NT – CoCr - QN/d12 2248.00 Premill abutment, BioniQ, NT – CoCr - QR/d12 2197.00 Premill abutment, BioniQ, AG – Ti QN/d12 2196.00 Premill abutment, BioniQ, AG – Ti QR/d12 2187.00 Premill abutment, BioniQ, NT – Ti QN/d12 2184.00 Premill abutment, BioniQ, NT – Ti QR/d12 2165.00 Massive abutment, BioniQ-QR/d5.2/L2			
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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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/5/24	MIT/2024/P085	Initial issue