

Esteemed

MEDACTA INTERNATIONAL S.A.
Strada Regina 6874
Castel San Pietro
Switzerland

Notified Body Confirmation Letter Reference: MDR 00033

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 Kiwa Cermet Italia S.p.A., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 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:

MEDACTA INTERNATIONAL S.A.
Strada Regina 6874
Castel San Pietro
Switzerland
SRN Number: CH-MF-000033473

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withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 the Notified Body,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

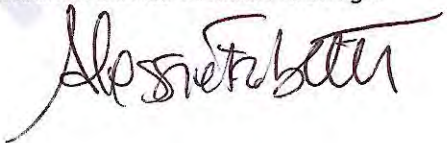
A handwritten signature in black ink, appearing to read "Alessia Frabetti". The signature is written in a cursive style with some loops and flourishes.

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
Hip orthopaedics implants MPACT 3D Metal Foam	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MPRES Implants	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Bipolar Head	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Monoblock acetabular Cup	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Romax E-Cross Acetabular Cup	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants APRICOT complete system	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MPACT Double Mobility	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MPACT System Implants	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Native System Implant	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Versafitcup	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants AMIS- K	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants AMIS- K LONG	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Cancellous Bone Screws	IIb not WET	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Double Mobility Converter	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Femoral Head; Endo Head	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A



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Hip orthopaedics implants Iliac Screw Mpac 3D Metal	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MasterLoc	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MectaCer Implants	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MEDACTA F-Cage	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MiniMAX	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MPACT 3D metal Augment	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MPACT 3D metal Multi-hole	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MPACT 3D metal Multi-hole thin	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MPACT 3D metal Two-hole	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants MPACT 3D Monocer Implants	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants M-Vizion Femoral Revision System	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Quadra S - Quadra H - Quadra C; Quadra Revision; Quadra P; AMISem H - AMISem C; AMISem H collared; AMISem H Proximal Coating; AMISem P; AMISem P Collared; Quadra P Anteverted; AMISem P Short Neck; Quadra P Short Neck	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Romax Resurfacing System	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Romax SensiTin Resurfacing Femoral Head	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants SMS Implants	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A



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Hip orthopaedics implants Versacem Metal Back cementato doppia mobilità / double motility Metal Back cemented	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants Versafitcup CC Trio; Versafitcup CC Trio No Hole	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Hip orthopaedics implants X -Acta	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK Hinge	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK Primary	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK Revision	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK Sphere	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants Moto Partial knee system	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants Moto Patello Femoral Joint Implant	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants 3D Metal Tibial and Diaphyseal Femoral Cone	IIb not WET	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants Anatomical Femoral component GMK SpheriKa	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants Anatomical Femoral component GMK SpheriKa coated	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants Femoral component GMK SpheriKa	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants Femoral component GMK SpheriKa coated	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK Sphere Revision Distal Wedge	IIb not WET	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK Sphere Revision Femoral Component	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A



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Knee orthopaedics implants GMK Sphere Revision Femoral Component Coated	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK Sphere Revision Offset	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK Sphere Revision Posterior Wedge	IIB not WET	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK Sphere Revision Tibial Tray	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK Sphere Revision Tibial Tray Coated	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Knee orthopaedics implants GMK UNI	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Shoulder orthopaedics implants Medacta Shoulder System TSA; Medacta Shoulder System Reverse	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Shoulder orthopaedics implants GRS baseplate	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Shoulder orthopaedics implants GRS central screw	IIB not WET	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Shoulder orthopaedics implants Humeral eccentric reverse metaphysis	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Orthopaedics implants for soft tissue fixation MectaLock C Composite Suture anchors	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Orthopaedics implants for soft tissue fixation Mectascrew C Composite Interference Screw	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Orthopaedics implants for soft tissue fixation MectaScrew B bioabsorbable interference screw	III	N/A	MED 29022A MED 29022D Kiwa Cermet Italia S.p.A
Surgical navigation system Nextar Shoulder Software	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Surgical navigation system NextAR Spine Software	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Surgical navigation system Passive Markers	Is	N/A	MED 29022C Kiwa Cermet Italia S.p.A



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Surgical navigation system and components NextAR Knee Software	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Medical software for the preoperative 3D planning and intraoperative verification for total hip replacement surgeries MyHip Planner	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Medical software for the preoperative 3D planning and intraoperative verification for total hip replacement surgeries MyHip Verifier	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Medical software for the preoperative 3D planning and intraoperative verification for surgeries MyPlanner Spine	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Medical software for the preoperative 3D planning and intraoperative verification for surgeries WebPlanner Spine	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Preoperative software planning for total hip arthroplasty Advanced MyHip Planner	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Surgical instruments for arthroscopy MectaScope - Scope 30° ; MectaScope - Scope 70° ,Sheath	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Surgical instruments for arthroscopy Soft Tissue Instruments MectaFlip	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Surgical instruments for arthroscopy Coated K-Wire, Coated Passing Wire	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Surgical instruments for arthroscopy MectaQTH	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Spinal surgical instruments MIS Blades	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Disposable instruments for orthopaedic implants Shoulder disposable k-wire - Ø2.5	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Disposable instruments for orthopaedic implants Shoulder disposable pin pack	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Disposable instruments for orthopaedic implants FastShuttle – Suture Passer	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A



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Disposable instruments for orthopaedic implants Modular Tap 2 Lead sterile	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic hip trial Trial Augments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic hip trial Trial Cages	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic hip trial Trial Cups	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic hip trial Trial Heads	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic hip trial Trial Liners	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic hip trial Trial Necks	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic hip trial Trial Olives	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic hip trial Trial Stems	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial 3D Metal Femoral Cone	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial E-cross trial insert	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial GMK Revision/Hinge trial components	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial GMK Sphere revision trial components	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial GMK Sphere ultimate finishing trial components	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Spherika Trial Femoral Component	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A



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Instruments for orthopaedic knee trial Trial Augments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial Cones	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial Extension Stems	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial Femoral Components	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial Inserts	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial Offset	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial Patella	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial Posterostabilized CAM & PEG	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial Tibia Components	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial tibial inserts - 7mm	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial tibial tray (Lateral & Medial) cementless	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic knee trial Trial Trochlea / Trial Box / trial Pegs / Trial Pivot	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic shoulder trial	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic spinal trial	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic implants GRS central peg reamer	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic implants GRS Line to line central peg reamer	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic implants GRS monoblock central peg reamer	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A



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Instruments for orthopaedic implants Trial Humeral Eccentric Reverse Metaphysis	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic implants Hip Arthro - Access Kit	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Instruments for orthopaedic implants Hip Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Adaptors	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants AMIS Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Bayonet drills / Drill bits	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Broaches	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Conical central peg reamer for baseplate	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Drill Bits	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Femoral Head Removal Pin	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants GMK Revision Spherical Reamer	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants GMK-Sphere Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Iliac Screw Mpac 3D metal	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Long and Thin Motoriz Screwdriv 3.5mm Hudson conn	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants MectaBlades – Cup Removal	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Monobloc central peg reamer	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A



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Reusable instruments for orthopaedic implants Monobloc glenoid + glenosphere reamer	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Monobloc starter drill – cannulated	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Monobloc starter drill - not cannulated	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - Lateral Side – Trial Base	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - Lateral Side – Trial Femur	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - Medial Side – Drill	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - Medial Side – Drill 6.5 mm medial UNI	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - Medial Side – Trial Base	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - Medial Side – Trial Femur	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - Medial Side – Trial Insert	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A



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Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - PFJ Drill Box	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - PFJ Drill Contour	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - PFJ Peg housing	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - PFJ Trial Implant	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Moto Partial Knee System Instruments - Trial Insert - Lateral UNI	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Motor Driven Knee Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Motorized handles	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants MUST MC Blades	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants MUST MIS	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants MUST Sacro Iliac Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants M-Vizion Hip Trial Distal Stem	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants M-Vizion Hip Trial Locking Screw	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants M-Vizion Hip Trial Proximal Body	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Nozzled glenoid reamer	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Oval glenoid reamer	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A



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
Reusable instruments for orthopaedic implants Posterior Cervical Screw System Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Quick connect flexible drill shaft	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Reamer handles	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Reamers (femoral)	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Retractors	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Shoulder Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Spine Drills	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Trial liners Trial plates	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Disposable Retractor	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants FastShuttle CC – Suture Passer capsular closure	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants GMK Efficiency single use Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Reusable instruments for orthopaedic implants Hip General Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation instruments M-ARS ACL Instruments	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation instruments All-Suture anchors-drills	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation instruments MectaLock peek drills	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A



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Soft Tissue orthopaedic fixation instruments FastShuttle Labral Suture Passer - 45° L	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation instruments FastShuttle Labral Suture Passer - 45° R	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation instruments Labral Suture Passer – Crescent	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Navigation system surgical instruments Navigation Solid Drills	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Navigation system surgical instruments NextAR Spine Target Large	Im	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Navigation system surgical instruments Camera NextAR	Im	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Navigation system surgical instruments Tracker small NextAR	Im	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Navigation system surgical instruments Fiducial	Is	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Navigation system surgical instruments Sterile Navigation Solid Drills	Is	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Navigation system surgical instruments Navigation Pin	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Navigation system surgical instruments Sterile Navigation Pin	Ila	N/A	MED 29022C Kiwa Cermet Italia S.p.A
Spine devices MUST Mini Posterior Cervical Screw System Screws	Ilb not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MUST Mini Posterior Cervical Screw System Hooks	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Bone cerclage system Mbrace Cable	Ilb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Orthopaedics hip implants Cortical Bone Screw Rounded Head	Ilb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Orthopaedics hip implants Compression Polyaxial Locking Screw Ø6.5mm	Ilb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A



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
Fixation system for ligament reconstruction MectaScrew PEEK interference screw	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Fixation system for ligament reconstruction MUST MC Cross-Connector	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Fixation system for ligament reconstruction MUST MC Screws	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Fixation system for ligament reconstruction MUST Pedicle Screw Implant	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Fixation system for ligament reconstruction MUST SI Sacro-Iliac Joint screw	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Orthopaedic fixation system PAO Cortical Screws	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Non absorbable braided suture PowerKnot High Strength Suture	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine implants MUST LT - Pedicle screw system	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices Mecta-C; Mecta-C TiPeek	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Simple PEEK	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Simple TiPEEK	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone TiPEEK Cage	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Device PEEK	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Device TiPEEK	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Hybrid PEEK	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Peek Cage	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Hybrid TiPEEK	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Oblique PEEK	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Oblique TiPEEK	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A



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Spine devices MectaLif Posterior PEEK	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Posterior TiPEEK	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif TiPEEK Transforaminal	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Transforaminal	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices Mecta-C Stand-Alone Cage	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices Mecta-C Stand-Alone Plate	IIb not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices Mecta-C Stand-Alone Screw	IIb not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Orthopaedics hip implants MectaPlug PE	IIb not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Orthopaedics hip implants MectaPlug PE II	IIb not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Orthopaedics hip implants 3D Metal B-Cage	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Orthopaedics hip implants Distal Centralizer wingless; Distal Centralizer large; Proximal Centralizer small; Proximal centralizer large	IIb not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Orthopaedics hip implants Kerboull Cage	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Orthopaedics hip implants Reinforcement cages	III	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Orthopaedics hip implants X-ACTA Distal Centralizer	IIb not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Fixation system for ligament reconstruction FairFix Adjustable Button	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Fixation system for ligament reconstruction FairFix Adjustable Button Extender	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation system MectaLock All-Suture anchors	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation system MectaLock PEEK Suture anchors	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation system MectaLock TI Suture anchor	IIb WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A



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Soft Tissue orthopaedic fixation system MectaTap TI – Suture anchor	Iib WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation system SnugFit All-Suture anchors	Iib WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation system MectaFix Continuous Loop	Iib WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Soft Tissue orthopaedic fixation system M-ARS Implants	Iib WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices Cervical Plate	Iib not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand -alone Plate L5/S1	Iib not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Enhanced Screw	Iib not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Plate Flush	Iib not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Plate Hybrid	Iib not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Plate Simple	Iib not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Plate Long	Iib not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Screw	Iib not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A
Spine devices MectaLif Anterior Stand-alone Plate Lateral	Iib not WET	N/A	MED 29022B Kiwa Cermet Italia S.p.A

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
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Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/22	Rev. 0	Initial issue
2024/03/27	Rev. 1	Typing errors
2024/03/28	Rev. 2	Addition of item

For further information on the content of the letter or verification of the validity of the letter please contact medical@kiwa.com or phone at +39.051.4593.111

