Medacta International

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Medacta International SA
Manufacturer address and contact details	Strada Regina CH-6874 Castel San Pietro Switzerland
Single Registration Number (SRN) (if available)	CH-MF-000033473

Authorised Representative name (if applicable)	Medacta Italia S.r.l.
Authorised Representative address and contact details	Via Giorgio Stephenson, 94, 20157 Milano MI Italy
Single Registration Number (SRN) (if available)	IT-AR-000022505

Notified body name (if applicable)	Kiwa Cermet Italia S.p.A □ See attached schedule
Notified body number (if applicable)	0476 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	MED 29022A MED 29022D □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	31st December 2027 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

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[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

26/04/2024

Francesco Siccardi

CEO

Medacta International SA

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Hip orthopaedics implants MPACT 3D Metal Foam 01.45.xxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants MPRES Implants 01.37.xxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Bipolar Head 25060.xxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Monoblock acetabular Cup 01.41.xxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Romax E-Cross Acetabular Cup 01.28.xxxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants APRICOT complete system 25070.xxxxHC	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants MPACT Double Mobility	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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01.32.xxxMB; 01.26.xxxxM; 01.26.xxxxMHC						
Hip orthopaedics implants MPACT System Implants 01.32.xxxSH; 01.32.xxxDH; 01.32.xxxMH; 01.32.xxxRH; 01.31.xxTP; 01.32.xxxxHCT; 01.32.xxxxHCAT; 01.32.xxxxHC4; 01.32.xxxxHC10A; 01.32.xxxxHC8; 01.32.xxxxHC10A4; 01.32.xxx; 01.32.xxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Native System Implant 01.11.xxxxHC	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Versafitcup 01.26.xxxxAT; 01.26.xxxxHCT; 01.26.xxxxHCAT; 01.26.xxxxxx; 01.26.xxMB; 01.26.65.xx; 01.26.xxxxSTT	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants AMIS- K 01.20.0xx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants AMIS- K LONG 01.20.2xx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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Hip orthopaedics implants Cancellous Bone Screws 01.43.xxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Double Mobility Converter 01.32.xxxxCF	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Femoral Head; Endo Head 01.25 xxx; 25055.xxxx; 01.25.xxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Iliac Screw Mpact 3D Metal 01.44.xxx; 01.44.xxxxSH; 01.44.xxxxLH	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants MasterLoc 01.39.xxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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Hip orthopaedics implants MectaCer Implants 01.29.xxx; 01.29.xxxH; 01.29.xxxA	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants MEDACTA F-Cage 01.45.xxxxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants MiniMAX 01.13.10xL; 01.13.10xR	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants MPACT 3D metal Augment 01.38.xxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants MPACT 3D metal Multi-hole 01.38.xxxMH	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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Hip orthopaedics implants MPACT 3D metal Multi-hole thin 01.38.xxxMH	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants MPACT 3D metal Two-hole 01.38.xxxDH	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants MPACT 3D Monocer Implants 01.42.xxxMCC; 01.42.xxxMCCL	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants M-Vizion Femoral Revision System 01.22.xxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Quadra S - Quadra H - Quadra C; Quadra Revision; Quadra P; AMIStem H - AMIStem C; AMIStem H collared; AMIStem H Proximal Coating; AMIStem P; AMIStem P Collared; Quadra P Anteverted; AMIStem P Short Neck; Quadra P Short Neck	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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01.12.xxx; 01.12.xxSN; 01.18.xxx						
Hip orthopaedics implants Romax Resufacing System 01.28.xxFC	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Romax SensiTin Resurfacing Femoral Head 01.28.xxxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants SMS Implants 01.36.xxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants Versacem Metal Back cementato doppia mobilità / double motility Metal Back cemented 01.27.xxCMB	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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Hip orthopaedics implants Versfitcup CC Trio; Versafitcup CC Trio No Hole 01.26.45.xxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Hip orthopaedics implants X -Acta 01.21.xxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants GMK Hinge 02.xx.xxxxxx; 02.09.xxxx; 02-09.xxxxx; 02.09.xxxxxxx; 02.09.xxxxxxxxx; 02.09.xxxxxxxxxx; 02.07.xxxFDA	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants GMK Primary 02.07.xxxxR; 02.07.xxxxL; 02.07.xxxxSM; 02.07.xxxxMUC; 02.07.xxxxSF; 02.07.xxxxFUC; 02.07.xxxxPSF; 02.07.xxxxRP; 02.07.xxxxAPUC; 02.07.xxxxAPPS; 02.07.xxxxIP	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants GMK Revision 02.xx.xxxx; 02.xx.xxxxx; 02.xx.xxxxxx; 02.xx.xxxxxxxx; 02.xx.xxxxxxRMLL; 02.xx.xxxxxxLMRL; 02.xx.xxxxFPW; 02.xx.xxxxFDW; 02.xx.xxxxFDA	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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Knee orthopaedics implants GMK Sphere 02.12.xxxxR; 02.12.xxxxL; 02.12.xxTxIxR; 02.12.xxTxIxL;02.07.xxxxR; 02.07.xxxxL; 02.12.xxxxFL; 02.12.xxxxFR; 02.07.xxxxRP; 02.07.xxxxIP; 02.07.Fxxxxx; 02.12.ExxxxFL; 02.12.xxxxCLR; 02.12.xxxxCRR; 02.12.ExxxxFR; 02.12.ExxxxCRL; 02.12.ExxxxCRR; 02.12.xxxRP; 02.12.3DxxL; 02.12.3DxxR	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants Moto Partial knee system 02.18xxxRM; 02.18.xxxLM ; 02.18.TFxRM; 02.18.Ifx.xx.RM; 02.18.IFX.xx.LM; 02.18.xxxLLRL; 02.18.TFxRL; 02.18.TFxLL; 02.18.Ifx.xx.LLRL; 02.18.EIFx.xx.xxxx; 02.18.EIFx.xx.xx0	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants Moto Patello Femoral Joint Implant 02.15.xxxx; 02.15.xxxL; 02.15.xxxR; 02.15.Exxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants 3D Metal Tibial and Diaphyseal Femoral Cone 02.07.CXSxx; 02.07.CSxx; 02.07.CMxx; 02.07.CLxx; 02.07.ESxx; 02.07.Emxx; 02.07.Elxx; 02.07.FCSxx; 02.07.FCMxx; 02.07.FCLxx; 02.07.FCXLxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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Knee orthopaedics implants Anatomical Femoral component GMK SpheriKa 02.12.KAxxL; 02.12.KAxxR	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants Anatomical Femoral component GMK SpheriKa coated 02.12.KAxxL; 02.12.KAxxR	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants Femoral component GMK SpheriKa 02.12.KAxxR; 02.12.KAxxL; 02.12.KAxxxR; 02.12.KAxxxL	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants Femoral component GMK SpheriKa coated 02.12.KAxxL; 02.12.KAxxR	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants GMK Sphere Revision Distal Wedge 02.19DAxx – 02.19.DBxx – 02.19.DCxx – 02.19.DDxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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Knee orthopaedics implants GMK Sphere Revision Femoral Component 02.19.00xL; 02.19.00xR	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants GMK Sphere Revision Femoral Component Coated 02.19.01xL; 02.19.01xR	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants GMK Sphere Revision Offset 02.19.xxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants GMK Sphere Revision Posterior Wedge 02.19.PAxx – 02.19.PBxx – 02.19.PCxx – 02.19.PDxx – 02.19.PExx – 02.19.PFxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants GMK Sphere Revision Tibial Tray 02.19.TxxxL – 02.19.TxxxR	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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Knee orthopaedics implants GMK Sphere Revision Tibial Tray Coated 02.19.28TxxxL; 02.19.28TxxxR	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Knee orthopaedics implants GMK UNI 02.08xxxx; 02.08.TMx.RMLL; 02.08.TMx.LMLR; 02.08.IMx.xx; 02.08.xxxRMLL; 02.08.xxxLMRL; 02.08.TFx.LMRL;02.08.TFx.RMLL; 02.08.TFxx.LMRL; 02.08.TFxx.RMLL; 02.08.IFx.xx.LMRL; 02.08.IFx.xxRMLL; 02.08.CTx.xx.LMRL; 02.08.CTx.xx.RMLL	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Shoulder orthopaedics implants Medacta Shoulder System TSA; Medacta Shoulder System Reverse 04.01.xxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Shoulder orthopaedics implants GRS baseplate 04.01.03xx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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Shoulder orthopaedics implants GRS central screw 04.01.032x	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Shoulder orthopaedics implants Humeral eccentric reverse metaphysis 04.01.0284	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Orthopaedics implants for soft tissue fixation MectaLock C Composite Suture anchors 05.11.10x; 05.10.10x	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Orthopaedics implants for soft tissue fixation Mectascrew C Composite Interference Screw 05.05.0xxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	
Orthopaedics implants for soft tissue fixation MectaScrew B bioabsorbable interference screw 05.05.xxxx	MED29022A/ MED29022D	26-05-2024	Kiwa Cermet Italia S.p.A n. 0476	Kiwa Cermet Italia S.p.A n. 0476	31-12-2027	

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