

CERTIFICATE



EC Certificate
Design Examination According to
Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-18-527

We hereby declare that a design examination has been carried out on the devices listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of Annex II Section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.

Organization

TST RAKOR ve TIBBİ ALETLER
SANAYİ ve TİCARET LİMİTED ŞİRKETİ

Sanayi Mahallesi, Şehit Cevdet Çelenk Caddesi No:3 34912
Kurtköy, Pendik, İstanbul, Turkey

Product: Hip Prosthesis

The products defined at the enclosure which is the part of this certificate and contains ten page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.3345.09

Expiry Date: 03 June 2021

Full quality assurance system according to Medical Devices Directive 93/42/EEC Annex-II Section 3 certificate is also mandatory for class III devices covered by this certificate.

04 June 2018, İstanbul, Turkey

Head of Notified Body



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Design Examination

Medical Devices Directive 93/42/EEC Annex-II Section 4

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Concerned medical devices;

Product Name	Class
CALCAR REP. STEM	III
CALCAR REP. STEM COCRM - PC 10X25	CALCAR REP. STEM COCRM PC+HA COATED 10X25 MM
CALCAR REP. STEM COCRM - PC 10X35	CALCAR REP. STEM COCRM PC+HA COATED 10X35 MM
CALCAR REP. STEM COCRM - PC 10X45	CALCAR REP. STEM COCRM PC+HA COATED 10X45 MM
CALCAR REP. STEM COCRM - PC 12X25	CALCAR REP. STEM COCRM PC+HA COATED 12X25 MM
CALCAR REP. STEM COCRM - PC 12X35	CALCAR REP. STEM COCRM PC+HA COATED 12X35 MM
CALCAR REP. STEM COCRM - PC 12X45	CALCAR REP. STEM COCRM PC+HA COATED 12X45 MM
CALCAR REP. STEM COCRM - PC 14X25	CALCAR REP. STEM COCRM PC+HA COATED 14X25 MM
CALCAR REP. STEM COCRM - PC 14X35	CALCAR REP. STEM COCRM PC+HA COATED 14X35 MM
CALCAR REP. STEM COCRM - PC 14X45	CALCAR REP. STEM COCRM PC+HA COATED 14X45 MM
CALCAR REP. STEM COCRM - PC 16X25	CALCAR REP. STEM COCRM PC+HA COATED 16X25 MM
CALCAR REP. STEM COCRM - PC 16X35	CALCAR REP. STEM COCRM PC+HA COATED 16X35 MM
CALCAR REP. STEM COCRM - PC 16X45	CALCAR REP. STEM COCRM PC+HA COATED 16X45 MM
CALCAR REP. STEM COCRM - POLISHED 10X25	CALCAR REP. STEM COCRM PC+HA COATED 18X25 MM
CALCAR REP. STEM COCRM - POLISHED 10X35	CALCAR REP. STEM COCRM PC+HA COATED 18X35 MM
CALCAR REP. STEM COCRM - POLISHED 10X45	CALCAR REP. STEM COCRM PC+HA COATED 18X45 MM
CALCAR REP. STEM COCRM - POLISHED 12X25	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 10X25
CALCAR REP. STEM COCRM - POLISHED 12X35	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 10X35
CALCAR REP. STEM COCRM - POLISHED 12X45	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 10X45
CALCAR REP. STEM COCRM - POLISHED 14X25	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 12X25
CALCAR REP. STEM COCRM - POLISHED 14X35	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 12X35
CALCAR REP. STEM COCRM - POLISHED 14X45	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 12X45
CALCAR REP. STEM COCRM - POLISHED 16X25	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 14X25
CALCAR REP. STEM COCRM - POLISHED 16X35	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 14X35
CALCAR REP. STEM COCRM - POLISHED 16X45	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 14X45
CALCAR REP. STEM COCRM - HA 10X25	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 16X25
CALCAR REP. STEM COCRM - HA 10X35	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 16X35
CALCAR REP. STEM COCRM - HA 10X45	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 16X45
CALCAR REP. STEM COCRM - HA 12X25	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 18X25
CALCAR REP. STEM COCRM - HA 12X35	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 18X35
CALCAR REP. STEM COCRM - HA 12X45	CALCAR REP. STEM COCRM-CEMENTED-SANDBLASTED 18X45
CALCAR REP. STEM COCRM - HA 14X25	CALCAR REP. STEM COCRM - HA 16X25
CALCAR REP. STEM COCRM - HA 14X35	CALCAR REP. STEM COCRM - HA 16X35
CALCAR REP. STEM COCRM - HA 14X45	CALCAR REP. STEM COCRM - HA 16X45

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Concerned medical devices;

Product Name	Class
SUPRA ART-1 STEM	III
SUPRA ART-1 STEM PC&HA 6 MM	SUPRA ART-1 STEM PC 6 MM
SUPRA ART-1 STEM PC&HA 7 MM	SUPRA ART-1 STEM PC 7 MM
SUPRA ART-1 STEM PC&HA 8 MM	SUPRA ART-1 STEM PC 8 MM
SUPRA ART-1 STEM PC&HA 9 MM	SUPRA ART-1 STEM PC 9 MM
SUPRA ART-1 STEM PC&HA 10 MM	SUPRA ART-1 STEM PC 10 MM
SUPRA ART-1 STEM PC&HA 11 MM	SUPRA ART-1 STEM PC 11 MM
SUPRA ART-1 STEM PC&HA 12 MM	SUPRA ART-1 STEM PC 12 MM
SUPRA ART-1 STEM PC&HA 13 MM	SUPRA ART-1 STEM PC 13 MM
SUPRA ART-1 STEM PC&HA 14 MM	SUPRA ART-1 STEM PC 14 MM
SUPRA ART-1 STEM PC&HA 15 MM	SUPRA ART-1 STEM PC 15 MM
SUPRA ART-1 STEM PC&HA 16 MM	SUPRA ART-1 STEM PC 16 MM
SUPRA ART-1 STEM HA 6 MM	SUPRA ART-1 STEM 6 MM - CEMENTED
SUPRA ART-1 STEM HA 7 MM	SUPRA ART-1 STEM 7 MM - CEMENTED
SUPRA ART-1 STEM HA 8 MM	SUPRA ART-1 STEM 8 MM - CEMENTED
SUPRA ART-1 STEM HA 9 MM	SUPRA ART-1 STEM 9 MM - CEMENTED
SUPRA ART-1 STEM HA 10 MM	SUPRA ART-1 STEM 10 MM - CEMENTED
SUPRA ART-1 STEM HA 11 MM	SUPRA ART-1 STEM 11 MM - CEMENTED
SUPRA ART-1 STEM HA 12 MM	SUPRA ART-1 STEM 12 MM - CEMENTED
SUPRA ART-1 STEM HA 13 MM	SUPRA ART-1 STEM 13 MM - CEMENTED
SUPRA ART-1 STEM HA 14 MM	SUPRA ART-1 STEM 14 MM - CEMENTED
SUPRA ART-1 STEM HA 15 MM	SUPRA ART-1 STEM 15 MM - CEMENTED
SUPRA ART-1 STEM HA 16 MM	SUPRA ART-1 STEM 16 MM - CEMENTED
SUPRA ART-1 STEM SANDBLASTED 6 MM	SUPRA ART-1 STEM SANDBLASTED 12 MM
SUPRA ART-1 STEM SANDBLASTED 7 MM	SUPRA ART-1 STEM SANDBLASTED 13 MM
SUPRA ART-1 STEM SANDBLASTED 8 MM	SUPRA ART-1 STEM SANDBLASTED 14 MM
SUPRA ART-1 STEM SANDBLASTED 9 MM	SUPRA ART-1 STEM SANDBLASTED 15 MM
SUPRA ART-1 STEM SANDBLASTED 10 MM	SUPRA ART-1 STEM SANDBLASTED 16 MM
SUPRA ART-1 STEM SANDBLASTED 11 MM	

Product Name	Class
VOLUMED MODULAR STEM	III
VOLUMED MODULAR STEM S.S. 6 MM	VOLUMED MODULAR STEM S.S. 11 MM
VOLUMED MODULAR STEM S.S. 7.5 MM	VOLUMED MODULAR STEM S.S. 12.5 MM
VOLUMED MODULAR STEM S.S. 10 MM	VOLUMED MODULAR STEM S.S. 15 MM

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Product Name	Class
VOLUMED MODULAR STEM	III
VOLUMED MODULAR STEM CRNI-POLISHED 7.5 MM	MODULAR STRAIGHT STEM 7.5 MM(12-14)
VOLUMED MODULAR STEM CRNI-POLISHED 10 MM	MODULAR STRAIGHT STEM 10 MM(12-14)
VOLUMED MODULAR STEM CRNI-POLISHED 11 MM	MODULAR STRAIGHT STEM 11 MM(12-14)
VOLUMED MODULAR STEM CRNI-POLISHED 12.5 MM	MODULAR STRAIGHT STEM 12.5 MM(12-14)
VOLUMED MODULAR STEM CRNI-POLISHED 15 MM	MODULAR STRAIGHT STEM 15 MM(12-14)

Product Name	Class
MODULAR HEAD	III
MODULAR HEAD COCRMO 22 MM X SMALL 12-14	MODULAR HEAD CRNI 22 MM X SMALL 12-14
MODULAR HEAD COCRMO 22 MM SMALL 12-14	MODULAR HEAD CRNI 22 MM SMALL 12-14
MODULAR HEAD COCRMO 22 MM MEDIUM 12-14	MODULAR HEAD CRNI 22 MM MEDIUM 12-14
MODULAR HEAD COCRMO 22 MM LONG 12-14	MODULAR HEAD CRNI 22 MM LONG 12-14
MODULAR HEAD COCRMO 22 MM XLONG 12-14	MODULAR HEAD CRNI 22 MM XLONG 12-14
MODULAR HEAD COCRMO 28 MM X SMALL 12-14	MODULAR HEAD CRNI 28 MM X SMALL 12-14
MODULAR HEAD COCRMO 28 MM SMALL 12-14	MODULAR HEAD CRNI 28 MM SMALL 12-14
MODULAR HEAD COCRMO 28 MM MEDIUM 12-14	MODULAR HEAD CRNI 28 MM MEDIUM 12-14
MODULAR HEAD COCRMO 28 MM LONG 12-14	MODULAR HEAD CRNI 28 MM LONG 12-14
MODULAR HEAD COCRMO 28 MM XLONG 12-14	MODULAR HEAD CRNI 28 MM XLONG 12-14
MODULAR HEAD COCRMO 32 MM X SMALL 12-14	MODULAR HEAD CRNI 32 MM X SMALL 12-14
MODULAR HEAD COCRMO 32 MM SMALL 12-14	MODULAR HEAD CRNI 32 MM SMALL 12-14
MODULAR HEAD COCRMO 32 MM MEDIUM 12-14	MODULAR HEAD CRNI 32 MM MEDIUM 12-14
MODULAR HEAD COCRMO 32 MM LONG 12-14	MODULAR HEAD CRNI 32 MM LONG 12-14
MODULAR HEAD COCRMO 32 MM XLONG 12-14	MODULAR HEAD CRNI 32 MM XLONG 12-14
MODULAR HEAD COCRMO 36 MM X SMALL 12-14	MODULAR HEAD CRNI 36 MM XSMALL 12-14
MODULAR HEAD COCRMO 36 MM SMALL 12-14	MODULAR HEAD CRNI 36 MM SMALL 12-14
MODULAR HEAD COCRMO 36 MM MEDIUM 12-14	MODULAR HEAD CRNI 36 MM MEDIUM 12-14
MODULAR HEAD COCRMO 36 MM LONG 12-14	MODULAR HEAD CRNI 36 MM LONG 12-14
MODULAR HEAD COCRMO 36 MM XLONG 12-14	MODULAR HEAD CRNI 36 MM XLONG 12-14
MODULAR HEAD CRNI 38 MM 12-14	MODULAR HEAD CRNI 40 MM 14-16
MODULAR HEAD CRNI 40 MM 12-14	MODULAR HEAD CRNI 41 MM 14-16
MODULAR HEAD CRNI 42 MM 12-14	MODULAR HEAD CRNI 42 MM 14-16
MODULAR HEAD CRNI 44 MM 12-14	MODULAR HEAD CRNI 43 MM 14-16
MODULAR HEAD CRNI 46 MM 12-14	MODULAR HEAD CRNI 45 MM 14-16
MODULAR HEAD CRNI 48 MM 12-14	MODULAR HEAD CRNI 47 MM 14-16
MODULAR HEAD CRNI 50 MM 12-14	MODULAR HEAD CRNI 52 MM 14-16
MODULAR HEAD CRNI 52 MM 12-14	MODULAR HEAD CRNI 53 MM 14-16
MODULAR HEAD CRNI 54 MM 12-14	MODULAR HEAD CRNI 54 MM 14-16
MODULAR HEAD CRNI 56 MM 12-14	

04 June 2018, Istanbul, Turkey

Head of Notified Body

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Concerned medical devices;

Product Name	Class
ACETABULAR CUP	III
ACETABULAR CUP 0° 28X40 MM	ACETABULAR CUP 10° 28X40 MM
ACETABULAR CUP 0° 28X42 MM	ACETABULAR CUP 10° 28X42 MM
ACETABULAR CUP 0° 28X44 MM	ACETABULAR CUP 10° 28X44 MM
ACETABULAR CUP 0° 28X46 MM	ACETABULAR CUP 10° 28X46 MM
ACETABULAR CUP 0° 28X48 MM	ACETABULAR CUP 10° 28X48 MM
ACETABULAR CUP 0° 28X50 MM	ACETABULAR CUP 10° 28X50 MM
ACETABULAR CUP 0° 28X52 MM	ACETABULAR CUP 10° 28X52 MM
ACETABULAR CUP 0° 28X54 MM	ACETABULAR CUP 10° 28X54 MM
ACETABULAR CUP 0° 28X56 MM	ACETABULAR CUP 10° 28X56 MM
ACETABULAR CUP 0° 28X58 MM	ACETABULAR CUP 10° 28X58 MM
ACETABULAR CUP 0° 28X60 MM	ACETABULAR CUP 10° 28X60 MM
ACETABULAR CUP 0° 28X62 MM	ACETABULAR CUP 10° 28X62 MM
ACETABULAR CUP 0° 28X64 MM	ACETABULAR CUP 10° 28X64 MM
ACETABULAR CUP 0° 28X66 MM	ACETABULAR CUP 10° 28X66 MM
ACETABULAR CUP 20° 28X40 MM	ACETABULAR CUP E-POLLY 0° 28X40 MM
ACETABULAR CUP 20° 28X42 MM	ACETABULAR CUP E-POLLY 0° 28X42 MM
ACETABULAR CUP 20° 28X44 MM	ACETABULAR CUP E-POLLY 0° 28X44 MM
ACETABULAR CUP 20° 28X46 MM	ACETABULAR CUP E-POLLY 0° 28X46 MM
ACETABULAR CUP 20° 28X48 MM	ACETABULAR CUP E-POLLY 0° 28X48 MM
ACETABULAR CUP 20° 28X50 MM	ACETABULAR CUP E-POLLY 0° 28X50 MM
ACETABULAR CUP 20° 28X52 MM	ACETABULAR CUP E-POLLY 0° 28X52 MM
ACETABULAR CUP 20° 28X54 MM	ACETABULAR CUP E-POLLY 0° 28X54 MM
ACETABULAR CUP 20° 28X56 MM	ACETABULAR CUP E-POLLY 0° 28X56 MM
ACETABULAR CUP 20° 28X58 MM	ACETABULAR CUP E-POLLY 0° 28X58 MM
ACETABULAR CUP 20° 28X60 MM	ACETABULAR CUP E-POLLY 0° 28X60 MM
ACETABULAR CUP 20° 28X62 MM	ACETABULAR CUP E-POLLY 0° 28X62 MM
ACETABULAR CUP 20° 28X64 MM	ACETABULAR CUP E-POLLY 0° 28X64 MM
ACETABULAR CUP 20° 28X66 MM	ACETABULAR CUP E-POLLY 0° 28X66 MM
ACETABULAR CUP E-POLLY 10° 28X40 MM	ACETABULAR CUP E-POLLY 20° 28X40 MM
ACETABULAR CUP E-POLLY 10° 28X42 MM	ACETABULAR CUP E-POLLY 20° 28X42 MM
ACETABULAR CUP E-POLLY 10° 28X44 MM	ACETABULAR CUP E-POLLY 20° 28X44 MM
ACETABULAR CUP E-POLLY 10° 28X46 MM	ACETABULAR CUP E-POLLY 20° 28X46 MM
ACETABULAR CUP E-POLLY 10° 28X48 MM	ACETABULAR CUP E-POLLY 20° 28X48 MM
ACETABULAR CUP E-POLLY 10° 28X50 MM	ACETABULAR CUP E-POLLY 20° 28X50 MM
ACETABULAR CUP E-POLLY 10° 28X52 MM	ACETABULAR CUP E-POLLY 20° 28X52 MM
ACETABULAR CUP E-POLLY 10° 28X54 MM	ACETABULAR CUP E-POLLY 20° 28X54 MM
ACETABULAR CUP E-POLLY 10° 28X56 MM	ACETABULAR CUP E-POLLY 20° 28X56 MM
ACETABULAR CUP E-POLLY 10° 28X58 MM	ACETABULAR CUP E-POLLY 20° 28X58 MM
ACETABULAR CUP E-POLLY 10° 28X60 MM	ACETABULAR CUP E-POLLY 20° 28X60 MM
ACETABULAR CUP E-POLLY 10° 28X62 MM	ACETABULAR CUP E-POLLY 20° 28X62 MM
ACETABULAR CUP E-POLLY 10° 28X64 MM	ACETABULAR CUP E-POLLY 20° 28X64 MM
ACETABULAR CUP E-POLLY 10° 28X66 MM	ACETABULAR CUP E-POLLY 20° 28X66 MM



04 June 2018, Istanbul, Turkey

Head of Notified Body

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Concerned medical devices;

Product Name	Class
BIPOLAR HEAD	III
BIPOLAR HEAD COCRM 22X42 MM	BIPOLAR HEAD CRNI 28X40 MM
BIPOLAR HEAD COCRM 22X44 MM	BIPOLAR HEAD CRNI 28X42 MM
BIPOLAR HEAD COCRM 22X46 MM	BIPOLAR HEAD CRNI 28X44 MM
BIPOLAR HEAD COCRM 28X40 MM	BIPOLAR HEAD CRNI 28X46 MM
BIPOLAR HEAD COCRM 28X42 MM	BIPOLAR HEAD CRNI 28X48 MM
BIPOLAR HEAD COCRM 28X44 MM	BIPOLAR HEAD CRNI 28X50 MM
BIPOLAR HEAD COCRM 28X46 MM	BIPOLAR HEAD CRNI 28X52 MM
BIPOLAR HEAD COCRM 28X48 MM	BIPOLAR HEAD CRNI 28X54 MM
BIPOLAR HEAD COCRM 28X50 MM	BIPOLAR HEAD CRNI 28X56 MM
BIPOLAR HEAD COCRM 28X52 MM	BIPOLAR HEAD CRNI 28X58 MM
BIPOLAR HEAD COCRM 28X54 MM	BIPOLAR HEAD CRNI 28X60 MM
BIPOLAR HEAD COCRM 28X56 MM	BIPOLAR HEAD CRNI 28X62 MM
BIPOLAR HEAD COCRM 28X58 MM	BIPOLAR HEAD CRNI 28X64 MM
BIPOLAR HEAD COCRM 28X60 MM	BIPOLAR HEAD CRNI 28X66 MM
BIPOLAR HEAD COCRM 28X62 MM	BIPOLAR HEAD CRNI 32X48 MM
BIPOLAR HEAD COCRM 28X64 MM	BIPOLAR HEAD CRNI 32X50 MM
BIPOLAR HEAD COCRM 28X66 MM	BIPOLAR HEAD CRNI 32X52 MM
BIPOLAR HEAD COCRM 32X48 MM	BIPOLAR HEAD CRNI 32X54 MM
BIPOLAR HEAD COCRM 32X50 MM	BIPOLAR HEAD CRNI 32X56 MM
BIPOLAR HEAD COCRM 32X52 MM	BIPOLAR HEAD CRNI 32X58 MM
BIPOLAR HEAD COCRM 32X54 MM	BIPOLAR HEAD CRNI 32X60 MM
BIPOLAR HEAD COCRM 32X56 MM	BIPOLAR HEAD CRNI 32X62 MM
BIPOLAR HEAD COCRM 32X58 MM	BIPOLAR HEAD CRNI 32X64 MM
BIPOLAR HEAD COCRM 32X60 MM	BIPOLAR HEAD CRNI 32X66 MM
BIPOLAR HEAD COCRM 32X62 MM	BIPOLAR HEAD CRNI 36X48 MM
BIPOLAR HEAD COCRM 32X64 MM	BIPOLAR HEAD CRNI 36X50 MM
BIPOLAR HEAD COCRM 32X66 MM	BIPOLAR HEAD CRNI 36X52 MM
BIPOLAR HEAD COCRM 36X48 MM	BIPOLAR HEAD CRNI 36X54 MM
BIPOLAR HEAD COCRM 36X50 MM	BIPOLAR HEAD CRNI 36X56 MM
BIPOLAR HEAD COCRM 36X52 MM	BIPOLAR HEAD CRNI 36X58 MM
BIPOLAR HEAD COCRM 36X54 MM	BIPOLAR HEAD CRNI 36X60 MM
BIPOLAR HEAD COCRM 36X56 MM	BIPOLAR HEAD CRNI 36X62 MM
BIPOLAR HEAD COCRM 36X58 MM	BIPOLAR HEAD CRNI 36X64 MM
BIPOLAR HEAD COCRM 36X60 MM	BIPOLAR HEAD CRNI 36X66 MM
BIPOLAR HEAD COCRM 36X62 MM	
BIPOLAR HEAD COCRM 36X64 MM	
BIPOLAR HEAD COCRM 36X66 MM	



04 June 2018, Istanbul, Turkey

Head of Notified Body



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Concerned medical devices;

Product Name	Class
BIPOLAR HEAD	III
BIPOLAR HEAD E-POLLY COCRMO 28X40 MM	BIPOLAR HEAD E-POLLY CRNI 28X40 MM
BIPOLAR HEAD E-POLLY COCRMO 28X42 MM	BIPOLAR HEAD E-POLLY CRNI 28X42 MM
BIPOLAR HEAD E-POLLY COCRMO 28X44 MM	BIPOLAR HEAD E-POLLY CRNI 28X44 MM
BIPOLAR HEAD E-POLLY COCRMO 28X46 MM	BIPOLAR HEAD E-POLLY CRNI 28X46 MM
BIPOLAR HEAD E-POLLY COCRMO 28X48 MM	BIPOLAR HEAD E-POLLY CRNI 28X48 MM
BIPOLAR HEAD E-POLLY COCRMO 28X50 MM	BIPOLAR HEAD E-POLLY CRNI 28X50 MM
BIPOLAR HEAD E-POLLY COCRMO 28X52 MM	BIPOLAR HEAD E-POLLY CRNI 28X52 MM
BIPOLAR HEAD E-POLLY COCRMO 28X54 MM	BIPOLAR HEAD E-POLLY CRNI 28X54 MM
BIPOLAR HEAD E-POLLY COCRMO 28X56 MM	BIPOLAR HEAD E-POLLY CRNI 28X56 MM
BIPOLAR HEAD E-POLLY COCRMO 28X58 MM	BIPOLAR HEAD E-POLLY CRNI 28X58 MM
BIPOLAR HEAD E-POLLY COCRMO 28X60 MM	BIPOLAR HEAD E-POLLY CRNI 28X60 MM
BIPOLAR HEAD E-POLLY COCRMO 28X62 MM	BIPOLAR HEAD E-POLLY CRNI 28X62 MM
BIPOLAR HEAD E-POLLY COCRMO 28X64 MM	BIPOLAR HEAD E-POLLY CRNI 28X64 MM
BIPOLAR HEAD E-POLLY COCRMO 28X66 MM	BIPOLAR HEAD E-POLLY CRNI 28X66 MM

Product Name	Class
UNIPOLAR COMPONENTS	III
A. UNIPOLAR HEAD S.S. 40 MM 12-14	A. UNIPOLAR HEAD COCRMO 40 MM 12-14
A. UNIPOLAR HEAD S.S. 41 MM 12-14	A. UNIPOLAR HEAD COCRMO 42 MM 12-14
A. UNIPOLAR HEAD S.S. 42 MM 12-14	A. UNIPOLAR HEAD COCRMO 44 MM 12-14
A. UNIPOLAR HEAD S.S. 43 MM 12-14	A. UNIPOLAR HEAD COCRMO 46 MM 12-14
A. UNIPOLAR HEAD S.S. 44 MM 12-14	A. UNIPOLAR HEAD COCRMO 48 MM 12-14
A. UNIPOLAR HEAD S.S. 45 MM 12-14	A. UNIPOLAR HEAD COCRMO 50 MM 12-14
A. UNIPOLAR HEAD S.S. 46 MM 12-14	A. UNIPOLAR HEAD COCRMO 52 MM 12-14
A. UNIPOLAR HEAD S.S. 47 MM 12-14	A. UNIPOLAR HEAD COCRMO 54 MM 12-14
A. UNIPOLAR HEAD S.S. 48 MM 12-14	A. UNIPOLAR HEAD COCRMO 56 MM 12-14
A. UNIPOLAR HEAD S.S. 49 MM 12-14	UNIPOLAR HEAD CRNI 40 MM 12-14
A. UNIPOLAR HEAD S.S. 50 MM 12-14	UNIPOLAR HEAD CRNI 42 MM 12-14
A. UNIPOLAR HEAD S.S. 51 MM 12-14	UNIPOLAR HEAD CRNI 44 MM 12-14
A. UNIPOLAR HEAD S.S. 52 MM 12-14	UNIPOLAR HEAD CRNI 46 MM 12-14
A. UNIPOLAR HEAD S.S. 53 MM 12-14	UNIPOLAR HEAD CRNI 48 MM 12-14
A. UNIPOLAR HEAD S.S. 54 MM 12-14	UNIPOLAR HEAD CRNI 50 MM 12-14
A. UNIPOLAR HEAD S.S. 55 MM 12-14	UNIPOLAR HEAD CRNI 52 MM 12-14
A. UNIPOLAR HEAD S.S. 56 MM 12-14	UNIPOLAR HEAD CRNI 54 MM 12-14
	UNIPOLAR HEAD CRNI 56 MM 12-14



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Concerned medical devices;

Product Name	Class
UNIPOLAR COMPONENTS	III
A. UNIPOLAR RING COCRMO 12-14 LARGE A. UNIPOLAR RING COCRMO 12-14 MEDIUM A. UNIPOLAR RING COCRMO 12-14 SMALL A. UNIPOLAR RING COCRMO 12-14 X SMALL A. UNIPOLAR RING COCRMO 12-14 XLARGE A. UNIPOLAR RING S.S. 12-14 LARGE A. UNIPOLAR RING S.S. 12-14 MEDIUM A. UNIPOLAR RING S.S. 12-14 SMALL	A. UNIPOLAR RING S.S. 12-14 X LARGE A. UNIPOLAR RING S.S. 12-14 X SMALL A. UNIPOLAR RING TI 12-14 LARGE A. UNIPOLAR RING TI 12-14 MEDIUM A. UNIPOLAR RING TI 12-14 SMALL A. UNIPOLAR RING TI 12-14 X LARGE A. UNIPOLAR RING TI 12-14 X SMALL

Product Name	Class
PRESS FIT CUP COMPONENTS	III
ANAT. PRESS FIT CUP PC & HA COATED 44 MM ANAT. PRESS FIT CUP PC & HA COATED 46 MM ANAT. PRESS FIT CUP PC & HA COATED 48 MM ANAT. PRESS FIT CUP PC & HA COATED 50 MM ANAT. PRESS FIT CUP PC & HA COATED 52 MM ANAT. PRESS FIT CUP PC & HA COATED 54 MM ANAT. PRESS FIT CUP PC & HA COATED 56 MM ANAT. PRESS FIT CUP PC & HA COATED 58 MM ANAT. PRESS FIT CUP PC & HA COATED 60 MM ANAT. PRESS FIT CUP PC & HA COATED 62 MM ANAT. PRESS FIT CUP PC & HA COATED 64 MM ANAT. PRESS FIT CUP PC & HA COATED 66 MM INSERT FOR ANAT. PRESS FIT CUP 0° 44 MM E-POLLY INSERT FOR ANAT. PRESS FIT CUP 0° 44 MM UHMWPE INSERT FOR ANAT. PRESS FIT CUP 0° 46-48-50 MM E-POLLY INSERT FOR ANAT. PRESS FIT CUP 0° 46-48-50 MM UHMWPE INSERT FOR ANAT. PRESS FIT CUP 0° 52-54-56 MM E-POLLY	INSERT FOR ANAT. PRESS FIT CUP 0° 52-54-56 MM UHMWPE INSERT FOR ANAT. PRESS FIT CUP 0° 58-60 MM E-POLLY INSERT FOR ANAT. PRESS FIT CUP 0° 58-60 MM UHMWPE INSERT FOR ANAT. PRESS FIT CUP 0° 62-66 MM E-POLLY INSERT FOR ANAT. PRESS FIT CUP 0° 62-66 MM UHMWPE INSERT FOR ANAT. PRESS FIT CUP 10° 44 MM E-POLLY INSERT FOR ANAT. PRESS FIT CUP 10° 44 MM UHMWPE INSERT FOR ANAT. PRESS FIT CUP 10° 46-48-50 MM E-POLLY INSERT FOR ANAT. PRESS FIT CUP 10° 46-48-50 MM UHMWPE INSERT FOR ANAT. PRESS FIT CUP 10° 52-54-56 MM E-POLLY INSERT FOR ANAT. PRESS FIT CUP 10° 52-54-56 MM UHMWPE INSERT FOR ANAT. PRESS FIT CUP 10° 58-60 MM E-POLLY INSERT FOR ANAT. PRESS FIT CUP 10° 58-60 MM UHMWPE INSERT FOR ANAT. PRESS FIT CUP 10° 62-66 MM E-POLLY INSERT FOR ANAT. PRESS FIT CUP 10° 62-66 MM UHMWPE

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Concerned medical devices;

Product Name	Class
ARTHROM BODY	III
ARTHROM BODY LARGE JUNCTION HA SMALL 65 MM	ARTHROM MOD.HIP PRO.BODY NAR.JUNC.PC&HA
ARTHROM BODY LARGE JUNCTION HA STANDARD 75 MM	STAND.55MM
ARTHROM BODY LARGE JUNCTION SMALL 65 MM	ARTHROM MODULAR HIP PROT.BODY
ARTHROM BODY NARROW JUNCTION HA SMALL 45 MM	LARG.JUNC.STAND.65MM
ARTHROM BODY NARROW JUNCTION HA SMALL 55 MM	ARTHROM MODULAR HIP PROT.BODY
ARTHROM BODY NARROW JUNCTION HA STANDARD 55 MM	LARG.JUNC.STAND.75MM
ARTHROM BODY NARROW JUNCTION HA STANDARD 65 MM	ARTHROM MODULAR HIP PROT.BODY NAR.JUNC.SMALL
ARTHROM BODY NARROW JUNCTION PC+HA SMALL 45	55 MM
ARTHROM BODY NARROW JUNCTION SMALL 45	CALCAR ARTHROM STEM BODY 45X25
ARTHROM BODY NARROW JUNCTION STANDARD 55 MM	CALCAR ARTHROM STEM BODY 45X35
ARTHROM BODY POROUS SMALL 45	CALCAR ARTHROM STEM BODY 55X25
ARTHROM BODY POROUS SMALL 55	CALCAR ARTHROM STEM BODY 55X35
ARTHROM BODY POROUS SMALL 65	CALCAR ARTHROM STEM BODY 55X45
ARTHROM BODY POROUS STANDARD 55	CALCAR ARTHROM STEM BODY COLLARED 45
ARTHROM BODY POROUS STANDARD 65	CALCAR ARTHROM STEM BODY COLLARED 55
ARTHROM BODY POROUS STANDARD 75	CALCAR ARTHROM STEM BODY COLLARED NARROW 65
ARTHROM MOD.HIP PRO.BODY LARG.JUN.PC&HA SMALL 65MM	CALCAR ARTHROM STEM BODY COLLARED STANDARD 55
ARTHROM MOD.HIP PRO.BODY LARG.JUN.PC&HA	CALCAR ARTHROM STEM BODY COLLARED STANDARD 65
STAND.65MM	CALCAR ARTHROM STEM BODY NARROW 65X25
ARTHROM MOD.HIP PRO.BODY LARG.JUN.PC&HA	CALCAR ARTHROM STEM BODY NARROW 65X35
STAND.75MM	CALCAR ARTHROM STEM BODY NARROW 65X45
ARTHROM MOD.HIP PRO.BODY NAR.JUNC.PC&HA SMALL 55MM	CALCAR ARTHROM STEM BODY STANDARD 55X25
	CALCAR ARTHROM STEM BODY STANDARD 55X35
	CALCAR ARTHROM STEM BODY STANDARD 55X45
	CALCAR ARTHROM STEM BODY STANDARD 65X25
	CALCAR ARTHROM STEM BODY STANDARD 65X35
	CALCAR ARTHROM STEM BODY STANDARD 65X45

Product Name	Class
ARTHROM JUNCTION BOLT	III
ARTHROM JUNCTION BOLT FOR 45 MM BODY	
ARTHROM JUNCTION BOLT Ø12 MM	
ARTHROM JUNCTION BOLT Ø17 MM	
ARTHROM JUNCTION BOLT STANDARD	

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Concerned medical devices;

Product Name	Class
ARTHROM STEM	III
ARTHROM MOD.HIP PROT.STEM L.JUNC. HA Ø12-15X140	ARTHROM MOD.HIP PROT.STEM N.JUNC. HA Ø10-13X100
ARTHROM MOD.HIP PROT.STEM L.JUNC. HA Ø13-16X140	ARTHROM MOD.HIP PROT.STEM N.JUNC. HA Ø10-13X140
ARTHROM MOD.HIP PROT.STEM L.JUNC. HA Ø13-16X180	ARTHROM MOD.HIP PROT.STEM N.JUNC. HA Ø11-14X100
ARTHROM MOD.HIP PROT.STEM L.JUNC. HA Ø14-17X140	ARTHROM MOD.HIP PROT.STEM N.JUNC. HA Ø11-14X140
ARTHROM MOD.HIP PROT.STEM L.JUNC. HA Ø15-18X140	ARTHROM MOD.HIP PROT.STEM N.JUNC. HA Ø12-15X100
ARTHROM MOD.HIP PROT.STEM L.JUNC. HA Ø15-18X180	ARTHROM MOD.HIP PROT.STEM N.JUNC. HA Ø12-15X140
ARTHROM MOD.HIP PROT.STEM L.JUNC. HA Ø17-20X140	ARTHROM MOD.HIP PROT.STEM N.JUNC. HA Ø13-16X100
ARTHROM MOD.HIP PROT.STEM L.JUNC. HA Ø17-20X180	ARTHROM MOD.HIP PROT.STEM N.JUNC. HA Ø13-16X140
ARTHROM STEM LARGE JUNCTION PC+HA 17X140	ARTHROM STEM NARROW JUNCTION PC+HA 13X100
ARTHROM MOD.HIP PROT.STEM L.JUNC.PC+HA Ø12-15X140	ARTHROM STEM NARROW JUNCTION PC+HA 13X140
ARTHROM MOD.HIP PROT.STEM L.JUNC.PC+HA Ø13-16X140	ARTHROM STEM NARROW JUNCTION PC+HA 14X100
ARTHROM STEM LARGE JUNCTION PC+HA 16X180	ARTHROM STEM NARROW JUNCTION PC+HA 14X140
ARTHROM STEM LARGE JUNCTION PC+HA 18X140	ARTHROM STEM NARROW JUNCTION PC+HA 15X100
ARTHROM STEM LARGE JUNCTION PC+HA 18X180	ARTHROM STEM NARROW JUNCTION PC+HA 15X140
ARTHROM STEM LARGE JUNCTION PC+HA 20X140	ARTHROM STEM NARROW JUNCTION PC+HA 16X100
ARTHROM STEM LARGE JUNCTION PC+HA 20X180	ARTHROM STEM NARROW JUNCTION PC+HA 16X140
ARTHROM MOD.HIP PROT.STEM L.JUNC.S.B.C. Ø12-15X140	ARTHROM MOD.HIP PROT.STEM N.JUNC.S.B.C. Ø10-13X100
ARTHROM MOD.HIP PROT.STEM L.JUNC.S.B.C. Ø13-16X140	ARTHROM MOD.HIP PROT.STEM N.JUNC.S.B.C. Ø10-13X140
ARTHROM MOD.HIP PROT.STEM L.JUNC.S.B.C. Ø13-16X180	ARTHROM MOD.HIP PROT.STEM N.JUNC.S.B.C. Ø11-14X100
ARTHROM MOD.HIP PROT.STEM L.JUNC.S.B.C. Ø14-17X140	ARTHROM MOD.HIP PROT.STEM N.JUNC.S.B.C. Ø11-14X140
ARTHROM MOD.HIP PROT.STEM L.JUNC.S.B.C. Ø15-18X140	ARTHROM MOD.HIP PROT.STEM N.JUNC.S.B.C. Ø12-15X100
ARTHROM MOD.HIP PROT.STEM L.JUNC.S.B.C. Ø15-18X180	ARTHROM MOD.HIP PROT.STEM N.JUNC.S.B.C. Ø12-15X140
ARTHROM MOD.HIP PROT.STEM L.JUNC.S.B.C. Ø17-20X140	ARTHROM MOD.HIP PROT.STEM N.JUNC.S.B.C. Ø13-16X100
ARTHROM MOD.HIP PROT.STEM L.JUNC.S.B.C. Ø17-20X180	ARTHROM MOD.HIP PROT.STEM N.JUNC.S.B.C. Ø13-16X140
ARTHROM MODULAR HIP PROT.STEM LARG.JUNC.Ø12-15X140	
ARTHROM MODULAR HIP PROT.STEM LARG.JUNC.Ø13-16X140	
ARTHROM MODULAR HIP PROT.STEM LARG.JUNC.Ø13-16X180	
ARTHROM MODULAR HIP PROT.STEM LARG.JUNC.Ø14-17X140	
ARTHROM MODULAR HIP PROT.STEM NAR.JUNC.Ø13-16X140	
ARTHROM MODULAR HIP PROT.STEM LARG.JUNC.Ø15-18X140	
ARTHROM MODULAR HIP PROT.STEM LARG.JUNC.Ø15-18X180	
ARTHROM MODULAR HIP PROT.STEM LARG.JUNC.Ø17-20X140	
ARTHROM MODULAR HIP PROT.STEM LARG.JUNC.Ø17-20X180	
ARTHROM MODULAR HIP PROT.STEM NAR.JUNC.Ø12-15X100	
ARTHROM MODULAR HIP PROT.STEM NAR.JUNC.Ø12-15X140	
ARTHROM MODULAR HIP PROT.STEM NAR.JUNC.Ø13-16X100	
ARTHROM MODULAR HIP PROT.STEM NAR.JUNC.Ø11-14X140	
ARTHROM MODULAR HIP PROT.STEM NAR.JUNC.Ø10-13X140	
ARTHROM MODULAR HIP PROT.STEM NAR.JUNC.Ø11-14X100	
ARTHROM MODULAR HIP PROT.STEM NAR.JUNC.Ø10-13X100	

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Product Name	Class
ARTHROM STEM	III
ARTHROM STEM PC+HA 14X210	ARTHROM STEM SANDBLST.COAT. 14X210
ARTHROM STEM PC+HA 15X210	ARTHROM STEM SANDBLST.COAT. 15X210
ARTHROM STEM PC+HA 16X210	ARTHROM STEM SANDBLST.COAT. 16X210
ARTHROM STEM PC+HA 17X210	ARTHROM STEM SANDBLST.COAT. 17X210
ARTHROM STEM PC+HA 18X210	ARTHROM STEM SANDBLST.COAT. 18X210
ARTHROM STEM PC+HA 20X210	ARTHROM STEM SANDBLST.COAT. 20X210
ARTHROM STEM POROUS 14X140	ARTHROM STEM POROUS 17X140
ARTHROM STEM POROUS 15X140	ARTHROM STEM POROUS 18X140
ARTHROM STEM POROUS 16X140	ARTHROM STEM POROUS 20X140

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

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