



CERTIFICATE

EC Design-Examination Certificate

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2020.106.13244 the validity of the certificate M.2020.106.13244-1 will also end.

Company Name : Hipokrat Tıbbi Malzemeler İmalat ve Pazarlama A.Ş.

Company Address : Kemalpaşa Mah. 7407/6 Sok. No:10 Pınarbaşı Bornova İZMİR / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive – Annex II (Section 4)

Product : Sterile Primer Hip Prostheses - Class III
Sterile Tumour Hip Prostheses - Class III

Trademarks : HİPOKRAT

GMDN : 33175, 33581, 33695, 34076, 34190, 34191, 34223, 38799, 43167,
43168, 46646, 58084, 61271, 61556, 61560, 61561

Product Types are attached.

Certificate Number : M.2020.106.13244-1
Report Number : MD.3832.IB
Initial Assessment Date : 14.06.2019
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UDEM International Certification
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The EC design examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the aforementioned directive. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

Address: Mutfukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76

E-mail: info@udemltd.com.tr www.udem.com.tr





This document containing 3 (three) pages is the Annex of the Certificate with the revision number 02, with the number M.2020.106.13244-1 and with the registration date of 23.01.2020 and with the revision date of 25.03.2020 issued for "Hipokrat Tibbi Malzemeler İmalat ve Pazarlama A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

Product Sub-Components	Size	GMDN Code
Hip Prosthesis Systems		
Primer Hip Prosthesis Systems		
1. Femoral Component Systems		
1.1. Hola Hip Prosthesis System Cemented		
Hola Hip Prosthesis Cemented	Size : 0; Size : 1; Size : 2; Size : 3; Size : 4; Size : 5; Size : 6; Size : 7; Size : 8	34223
Hola Lateralized Hip Prosthesis Cemented	Size : 0; Size : 1; Size : 2; Size : 3; Size : 4; Size : 5; Size : 6; Size : 7; Size : 8	34223
Bone Plug	ø9mm; ø10mm; ø11mm; ø12mm; ø13mm; ø14mm; ø15mm; ø16mm; ø17mm; ø18mm; ø19mm; ø20mm; ø21mm; ø22mm; ø23mm; ø24mm	38799
Distal Centralizer	Size : 0; Size : 1; Size : 2; Size : 3; Size : 4; Size : 5; Size : 6; Size : 7; Size : 8	61271
1.2. Modular Straight Stem Hip Prosthesis System Cemented		
Modular Straight Stem Hip Prosthesis Cemented 12/14	7.5mm; 10mm; 11.25mm; 12.5mm; 13.75mm; 15mm; 16.25mm; 17.5mm; 20mm	34223
1.3. Alfa Hip Prosthesis System Uncemented		
Alfa Hip Prosthesis Uncemented (Sand Blasted) 12/14	Size : -2; Size : -1; Size : 0; Size : 1; Size : 2; Size : 3; Size : 4; Size : 5; Size : 6; Size : 7; Size : 8; Size : 9; Size : 10; Size : 11	34223
Alfa Hip Prosthesis Uncemented Porous Coated (Tips) 12/14	Size : -2; Size : -1; Size : 0; Size : 1; Size : 2; Size : 3; Size : 4; Size : 5; Size : 6; Size : 7; Size : 8; Size : 9; Size : 10; Size : 11	34191
Alfa Hip Prosthesis Uncemented Porous Coated (Ha) 12/14	Size : -2; Size : -1; Size : 0; Size : 1; Size : 2; Size : 3; Size : 4; Size : 5; Size : 6; Size : 7; Size : 8; Size : 9; Size : 10; Size : 11	34191
Alfa Hip Prosthesis Stopper	M6	61271
1.4. Truva Modular Primary Hip Prosthesis System Uncemented		
Proximal Primary Body Uncemented (Sand Blasted) 12/14	XSmall; Small; Medium; Large	34190
Proximal Primary Body Uncemented Porous Coated (Tips) 12/14	XSmall; Small; Medium; Large	34191
Proximal Primary Body Uncemented Porous Coated (Tips+Ha) 12/14	XSmall; Small; Medium; Large	34191
Proximal Primary Calcar Body Uncemented Porous Coated (Tips+Ha) 12/14	XSmall; Small; Medium; Large	34191
Stem Tapered Splined	ø14x115mm; ø15x115mm; ø16x115mm; ø17x115mm; ø18x115mm; ø19x115mm; ø20x115mm; ø14x150mm; ø15x150mm; ø16x150mm; ø17x150mm; ø18x150mm; ø19x150mm; ø20x150mm; ø14x190mm; ø15x190mm; ø16x190mm; ø17x190mm; ø18x190mm; ø19x190mm; ø20x190mm	33581
Stem Uncemented Porous Coated (Tips)	ø14x115mm; ø15x115mm; ø16x115mm; ø17x115mm; ø18x115mm; ø19x115mm; ø20x115mm; ø14x150mm; ø15x150mm; ø16x150mm; ø17x150mm; ø18x150mm; ø19x150mm; ø20x150mm; ø14x190mm; ø15x190mm; ø16x190mm; ø17x190mm; ø18x190mm; ø19x190mm; ø20x190mm	33581
Locking Bolt	XSmall; Small; Medium; Large	46646
1.5. Hola Hip Prosthesis System Uncemented		
Hola Hip Prosthesis Uncemented Porous Coated (Ha) 12/14	Size : 0; Size : 1; Size : 2; Size : 3; Size : 4; Size : 5; Size : 6; Size : 7; Size : 8; Size : 9; Size : 10	34191
Hola Hip Prosthesis Uncemented Porous Coated (Tips+Ha) 12/14	Size : 0; Size : 1; Size : 2; Size : 3; Size : 4; Size : 5; Size : 6; Size : 7; Size : 8; Size : 9; Size : 10	34191
Hola Lateralized Hip Prosthesis Uncemented Porous Coated (Ha) 12/14	Size : 0; Size : 1; Size : 2; Size : 3; Size : 4; Size : 5; Size : 6; Size : 7; Size : 8; Size : 9; Size : 10	34191
Hola Lateralized Hip Prosthesis Uncemented Porous Coated (Tips+Ha) 12/14	Size : 0; Size : 1; Size : 2; Size : 3; Size : 4; Size : 5; Size : 6; Size : 7; Size : 8; Size : 9; Size : 10	34191
2. Modular Head Systems		
2.1. Modular Head for Total Hip Prostheses		
Modular Head for Total Hip Prosthesis 12/14	ø22 = Short (-2); Medium (Std); Long (+2) ø26 = Short (-4); Medium (Std); Long (+4); (with Neck) XLong (+8); (with Neck) XXLong (+12) ø28 = Short (-4); Medium (Std); Long (+4); (with Neck) XLong (+8); (with Neck) XXLong (+12) ø32 = Short (-4); Medium (Std); Long (+4); (with Neck) XLong (+8); (with Neck) XXLong (+12) ø36 = Short (-4); Medium (Std); Long (+4); (with Neck) XLong (+8); (with Neck) XXLong (+12)	33175
Modular Sleeve for Hip Prosthesis Cone	10/12 - 12/14	33175
2.2. Modular Head for Hemi Prostheses		



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Partial Head for Hemi Prosthesis 12/14	ø38mm; ø40mm; ø42mm; ø44mm; ø46mm; ø48mm; ø50mm; ø52mm; ø54mm; ø56mm; ø58mm; ø60mm	33175
2.3. Bipolar Head		
Bipolar Cup ø22mm	ø36mm; ø37mm; ø38mm	33695
Bipolar Cup ø26mm	ø39mm; ø40mm	33695
Bipolar Cup ø28mm	ø41mm; ø42mm; ø43mm; ø44mm; ø45mm; ø46mm; ø47mm; ø48mm; ø49mm; ø50mm; ø51mm; ø52mm; ø53mm; ø54mm; ø55mm; ø56mm; ø57mm; ø58mm; ø59mm; ø60mm	33695
3. Acetabular Component Systems		
3.1. Cemented Muller Type Acetabular Cup		
Muller Type Acetabular Cup	ø40x28mm; ø42x28mm; ø44x28mm; ø46x28mm; ø48x28mm; ø50x28mm; ø52x28mm; ø54x28mm; ø56x28mm; ø58x28mm; ø44x32mm; ø46x32mm; ø48x32mm; ø50x32mm; ø52x32mm; ø54x32mm; ø56x32mm; ø58x32mm; ø50x36mm; ø52x36mm; ø54x36mm; ø56x36mm; ø58x36mm	34076
High Cross Linked Muller Type Acetabular Cup	ø40x28mm; ø42x28mm; ø44x28mm; ø46x28mm; ø48x28mm; ø50x28mm; ø52x28mm; ø54x28mm; ø56x28mm; ø58x28mm; ø44x32mm; ø46x32mm; ø48x32mm; ø50x32mm; ø52x32mm; ø54x32mm; ø56x32mm; ø58x32mm; ø50x36mm; ø52x36mm; ø54x36mm; ø56x36mm; ø58x36mm	34076
Muller Type Acetabular Cup Cemented Angled	ø42x28mm; ø44x28mm; ø46x28mm; ø48x28mm; ø50x28mm; ø52x28mm; ø54x28mm; ø56x28mm; ø58x28mm; ø44x32mm; ø46x32mm; ø48x32mm; ø50x32mm; ø52x32mm; ø54x32mm; ø56x32mm; ø58x32mm; ø50x36mm; ø52x36mm; ø54x36mm; ø56x36mm; ø58x36mm	34076
High Cross Linked Muller Type Acetabular Cup Cemented Angled	ø44x32mm; ø46x32mm; ø48x32mm; ø50x32mm; ø52x32mm; ø54x32mm; ø56x32mm; ø58x32mm; ø42x28mm; ø44x28mm; ø46x28mm; ø48x28mm; ø50x28mm; ø52x28mm; ø54x28mm; ø56x28mm; ø58x28mm; ø50x36mm; ø52x36mm; ø54x36mm; ø56x36mm; ø58x36mm	34076
3.2. Duo Cup and Liner System		
Duo Cup Cemented	ø44mm; ø46mm; ø48mm; ø50mm; ø52mm; ø54mm; ø56mm; ø58mm; ø60mm; ø62mm	43167
Duo Cup Uncemented Porous Coated (Tips)	ø44mm; ø46mm; ø48mm; ø50mm; ø52mm; ø54mm; ø56mm; ø58mm; ø60mm; ø62mm	43167
Duo Cup Uncemented Porous Coated (Tips+Ha)	ø44mm; ø46mm; ø48mm; ø50mm; ø52mm; ø54mm; ø56mm; ø58mm; ø60mm; ø62mm	43167
Duo Cup Insert	ø28mm Head = ø44-ø46mm; ø48-ø50mm; ø52-ø54mm; ø56-ø58mm; ø60-ø62mm	43168
3.3. Press Fit Acetabular Cup and Liner Systems		
Acetabular Cup Uncemented (Sand Blasted)	ø42mm - Size AA; ø44mm - Size AA; ø46mm - Size A; ø48mm - Size A; ø50mm - Size B; ø52mm - Size B; ø54mm - Size C; ø56mm - Size C; ø58mm - Size D; ø60mm - Size D; ø62mm - Size E; ø64mm - Size E; ø66mm - Size F; ø68mm - Size F	43167
Acetabular Cup Uncemented Porous Coated (Tips)	ø42mm - Size AA; ø44mm - Size AA; ø46mm - Size A; ø48mm - Size A; ø50mm - Size B; ø52mm - Size B; ø54mm - Size C; ø56mm - Size C; ø58mm - Size D; ø60mm - Size D; ø62mm - Size E; ø64mm - Size E; ø66mm - Size F; ø68mm - Size F	43167
Acetabular Cup Multi Holes Uncemented Porous Coated (Tips)	ø42mm - Size AA; ø44mm - Size AA; ø46mm - Size A; ø48mm - Size A; ø50mm - Size B; ø52mm - Size B; ø54mm - Size C; ø56mm - Size C; ø58mm - Size D; ø60mm - Size D; ø62mm - Size E; ø64mm - Size E; ø66mm - Size F; ø68mm - Size F	43167
Acetabular Cup Uncemented Porous Coated (Tips+Ha)	ø42mm - Size AA; ø44mm - Size AA; ø46mm - Size A; ø48mm - Size A; ø50mm - Size B; ø52mm - Size B; ø54mm - Size C; ø56mm - Size C; ø58mm - Size D; ø60mm - Size D; ø62mm - Size E; ø64mm - Size E; ø66mm - Size F; ø68mm - Size F	43167
Acetabular Cup Multi Holes Uncemented Porous Coated (Tips+Ha)	ø42mm - Size AA; ø44mm - Size AA; ø46mm - Size A; ø48mm - Size A; ø50mm - Size B; ø52mm - Size B; ø54mm - Size C; ø56mm - Size C; ø58mm - Size D; ø60mm - Size D; ø62mm - Size E; ø64mm - Size E; ø66mm - Size F; ø68mm - Size F	43167
Protruded Liner for Acetabular Cup	0° = ø42-44mm Size AA ø22mm; ø46-48mm Size A ø26mm; ø42-44mm Size AA ø26mm; ø46-48mm Size A ø28mm; ø50-52mm Size B ø28mm; ø54-56mm Size C ø28mm; ø58-60mm Size D ø28mm; ø62-64mm Size E ø28mm; ø66-68mm Size F ø28mm; ø50-52mm Size B ø32mm; ø54-56mm Size C ø32mm; ø58-60mm Size D ø32mm; ø62-64mm Size E ø32mm; ø66-68mm Size F ø32mm; ø58-60mm Size D ø36mm; ø62-64mm Size E ø36mm; ø66-68mm Size F ø36mm 10° = ø42-44mm Size AA ø22mm; ø46-48mm Size A ø26mm; ø42-44mm Size AA 10° ø26mm; ø46-48mm Size A ø28mm; ø50-52mm Size B ø28mm; ø54-56mm Size C ø28mm; ø58-60mm Size D ø28mm; ø62-64mm Size E ø28mm; ø66-68mm Size F ø28mm; ø50-52mm Size B ø32mm; ø54-56mm Size C ø32mm; ø58-60mm Size D ø32mm; ø62-64mm Size E ø32mm; ø66-68mm Size F ø32mm; ø58-60mm Size D ø36mm; ø62-64mm Size E ø36mm; ø66-68mm Size F ø36mm 20° = ø42-44mm Size AA ø22mm; ø46-48mm Size A ø26mm; ø42-44mm Size AA ø26mm; ø46-48mm Size A ø28mm; ø50-52mm Size B ø28mm; ø54-56mm Size C ø28mm; ø58-	43168

	60mm Size D ø28mm; ø62-64mm Size E ø28mm; ø66-68mm Size F ø28mm; ø50-52mm Size B ø32mm; ø54-56mm Size C ø32mm; ø58-60mm Size D ø32mm; ø62-64mm Size E ø32mm; ø66-68mm Size F ø32mm; ø58-60mm Size D ø36mm; ø62-64mm Size E ø36mm; ø66-68mm Size F ø36mm	
High Cross Linked Protruded Liner for Acetabular Cup	0° = ø42-44mm Size AA ø22mm; ø46-48mm Size A ø26mm; ø42-44mm Size AA ø26mm; ø46-48mm Size A ø28mm; ø50-52mm Size B ø28mm; ø54-56mm Size C ø28mm; ø58-60mm Size D ø28mm; ø62-64mm Size E ø28mm; ø66-68mm Size F ø28mm; ø50-52mm Size B ø32mm; ø54-56mm Size C ø32mm; ø58-60mm Size D ø32mm; ø62-64mm Size E ø32mm; ø66-68mm Size F ø32mm; ø58-60mm Size D ø36mm; ø62-64mm Size E ø36mm; ø66-68mm Size F ø36mm 10° = ø42-44mm Size AA ø22mm; ø46-48mm Size A ø26mm; ø42-44mm Size AA ø26mm; ø46-48mm Size A ø28mm; ø50-52mm Size B ø28mm; ø54-56mm Size C ø28mm; ø58-60mm Size D ø28mm; ø62-64mm Size E ø28mm; ø66-68mm Size F ø28mm; ø50-52mm Size B ø32mm; ø54-56mm Size C ø32mm; ø58-60mm Size D ø32mm; ø62-64mm Size E ø32mm; ø66-68mm Size F ø32mm; ø58-60mm Size D ø36mm; ø62-64mm Size E ø36mm; ø66-68mm Size F ø36mm 20° = ø42-44mm Size AA ø22mm; ø46-48mm Size A ø26mm; ø42-44mm Size AA ø26mm; ø46-48mm Size A ø28mm; ø50-52mm Size B ø28mm; ø54-56mm Size C ø28mm; ø58-60mm Size D ø28mm; ø62-64mm Size E ø28mm; ø66-68mm Size F ø28mm; ø50-52mm Size B ø32mm; ø54-56mm Size C ø32mm; ø58-60mm Size D ø32mm; ø62-64mm Size E ø32mm; ø66-68mm Size F ø32mm; ø58-60mm Size D ø36mm; ø62-64mm Size E ø36mm; ø66-68mm Size F ø36mm	43168
Cancellous Screw	ø6.5x15mm; ø6.5x20mm; ø6.5x25mm; ø6.5x30mm; ø6.5x35mm; ø6.5x40mm; ø6.5x45mm; ø6.5x50mm; ø6.5x55mm; ø6.5x60mm; ø6.5x65mm	46646
3.4. Acetabular Cage		
Acetabular Cage	11 Holes = ø44mm; ø46mm; ø48mm; ø50mm 14 Holes = ø52mm; ø54mm; ø56mm; ø58mm	43167
Acetabular Reinforcement Cage	Left = ø44mm; ø46mm; ø48mm ; ø50mm; ø52mm; ø54mm; ø56mm; ø58mm Right = ø44mm; ø46mm; ø48mm; ø50mm; ø52mm; ø54mm; ø56mm; ø58mm	43167
Acetabular Roof Reinforcement Cage with Hook	ø36mm; ø38mm; ø40mm; ø42mm; ø44mm; ø46mm; ø48mm; ø50mm; ø52mm; ø54mm; ø56mm; ø58mm; ø60mm; ø62mm; ø64mm	43167
3.5. Pelvic Component		
Pelvic Component	ø48mm ; ø50mm; ø52mm; ø54mm; ø56mm; ø58mm; ø60mm; ø62mm; ø64mm	43167
Pelvic Splined Stem	ø8mm ; ø9mm; ø10mm	46646
Pelvic Stem Connection Bolt	M5	46646

Tumour Hip Prosthesis System

1. Tumour Hip Prosthesis System		
1.1. HBRS Tumour System		
Proximal Femur Full Resection Prosthesis 12/14		61561
Puller Bolt		46646
Extension Piece with Threaded	40mm; 50mm; 60mm; 70mm; 80mm; 90mm; 100mm; 110mm; 120mm	58084
Connection Piece	Male-Male; Female-Female	58084
Adapter	Male-Male	58084
Curved Large Conical Modular Stem Cemented	ø10x80mm; ø10x100mm; ø10x120mm; ø10x130mm; ø11x80mm; ø11x100mm; ø11x120mm; ø11x130mm; ø12x80mm; ø12x100mm; ø12x120mm; ø12x130mm; ø13x130mm; ø14x130mm; ø15x130mm; ø16x130mm	61560
Curved Large Conical Modular Stem Uncemented (Tips)	AA10x80mm; AA10x100mm; AA10x120mm; AA10x130mm; AA11x80mm; AA11x100mm; AA11x120mm; AA11x130mm; AA12x80mm; AA12x100mm; AA12x120mm; AA12x130mm; AA13x80mm; AA13x100mm; AA13x120mm; AA13x130mm; AA14x130mm; AA15x130mm; AA16x130mm	61556
Curved Large Conical Modular Stem Uncemented (Tips+Ha)	AA10x80mm; AA10x100mm; AA10x120mm; AA10x130mm; AA11x80mm; AA11x100mm; AA11x120mm; AA11x130mm; AA12x80mm; AA12x100mm; AA12x120mm; AA12x130mm; AA13x80mm; AA13x100mm; AA13x120mm; AA13x130mm; AA14x130mm; AA15x130mm; AA16x130mm	61556
Bone Plug	ø13mm; ø14mm; ø15mm; ø16mm; ø17mm; ø18mm; ø19mm	38799