



EC DESIGN EXAMINATION CERTIFICATE

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

With the expire of the certificate M.2020.106.13652 the validity of the certificate
M.2020.106.13652-1 will also end.

Company Name : Beijing Chunlizhengda Medical Instruments Co., Ltd.

Company Address : No. 10, Xinmi West 2nd Road, South District, Tongzhou Economic
Development Zone, Tongzhou District, Beijing, China

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

Product : Sterile Hip Prosthesis System - Class III
Sterile Knee Prosthesis System - Class III

GMDN : 34204, 33181, 33715, 61786, 32831, 32832, 34199, 46585, 48066

Product Types are attached.

Certificate Number : M.2020.106.13652-1

Report Number : MD.4055.IB

Initial Assessment Date : 24.12.2019

Registration Date : 23.06.2020

Revision Date /No : 25.05.2021/02

Expiry Date : 27.05.2024



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 applies 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 expiry date 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.

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EC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2020.106.13652-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : Beijing Chunlizhengda Medical Instruments Co., Ltd.

Company Address : No. 10, Xinmi West 2nd Road, South District, Tongzhou Economic Development Zone, Tongzhou District, Beijing, China

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

Product : Sterile Hip Prosthesis System - Class III
Sterile Knee Prosthesis System - Class III

GMDN : 34204, 33181, 33715, 61786, 32831, 32832, 34199, 46585, 48066

Product Types are attached.

Certificate Number : M.2020.106.13652

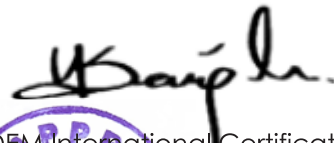
Report Number : MD.4055.IB

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Revision Date /No : 25.05.2021/02

Expiry Date : 27.05.2024


UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. 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 expiry date of this certificate in question, the mentioned



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Hip Prosthesis - Class III - Sterile

Product Name	Model	Material	Product Size	GMDN Code
Acetabular Cup	58	Ti6Al4V	φ40, φ42, φ44, φ46, φ48, φ50, φ52, φ54, φ56, φ58, φ60, φ62, φ64, φ66, φ68, φ70, φ72	34204
Bipolar Head	M	CoCrMo	φ38, φ40, φ41, φ42, φ43, φ44, φ45, φ46, φ47, φ48, φ49, φ50, φ51, φ52, φ53, φ54, φ55, φ56, φ57, φ58, φ59, φ60	61786
Femoral Head	T	CoCrMo	22-0, 22-3, 22-6, 22-9, 28-0, 28-3, 28-6, 28-9, 32-(-6), 32-(-3), 32-0, 32-3, 32-6, 32-9, 36-(-6), 36-(-3), 36-0, 36-3, 36-6, 36-9	33181
Liner	58	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	58	HXLPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	JS	Ceramic	28/35, 28/37, 32/39, 36/44, 36/48, 36/52	34204
Femoral Head	TB	Ceramic	36S, 36M, 36L, 32S, 32M, 32L, 32XL, 36XL, 28S, 28M, 28L	34204
Femoral Stem	140	Ti6Al4V	9#, 10#, 11#, 12#, 13#, 14#, 15#	34204
Femoral Stem	BE	Ti6Al4V	8#, 9#, 10#, 11#, 12#, 13#, 14#, 15#, 16#, 17#, 18#	34204
Titanium Screw	6	Ti6Al4V	15mm, 16mm, 17mm, 18mm, 19mm, 20mm, 21mm, 22mm, 23mm, 24mm, 25mm, 26mm, 27mm, 28mm, 29mm, 30mm, 31mm, 32mm, 33mm, 34mm, 35mm, 36mm, 37mm, 38mm, 39mm, 40mm, 41mm, 42mm, 43mm, 44mm, 45mm, 46mm, 47mm, 48mm, 49mm, 50mm, 51mm, 52mm, 53mm, 54mm, 55mm, 56mm, 57mm, 58mm, 59mm, 60mm, 61mm, 62mm, 63mm, 64mm, 65mm, 66mm, 67mm, 68mm, 69mm, 70mm, 71mm, 72mm, 73mm, 74mm, 75mm, 76mm, 77mm, 78mm, 79mm, 80mm	34204
Femoral Stem	130	Ti6Al4V	6#, 7#, 8#, 9#, 10#, 11#, 12#	34204
Femoral Stem	145	Ti6Al4V	7#, 8#, 9#, 10#, 11#, 12#, 13#, 14#	34204



This document containing 5 (five) pages is the Annex of the Certificate with the revision number 02, with the number M.2020.106.13652-1 and with the registration date of 23.06.2020 and with the revision date of 25.05.2021 issued for "Beijing Chunlizhengda Medical Instruments Co., Ltd." 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.

Femoral Stem	155	Ti6Al4V	8#, 9#, 10#, 11#, 12#, 13#, 14#, 15#, 16#	34204
Femoral Stem	160	Ti6Al4V	150-9,150-10,150-11,150-12,150-13,150-14,150-15,150-16,150-18,150-20	34204
Femoral Stem	BE1	Ti6Al4V	6#, 7#, 8#, 9#, 10#, 11#, 12#, 13#	
Femoral Stem	BE2	Ti6Al4V	127H-6,127H-7,127H-8,127H-9,127H-10,127H-11,127H-12,127H-13,127H-14,127H-15,127H-16,127H-17,127H-18,133H-6,133H-7,133H-8,133H-9,133H-10,133H-11,133H-12,133H-13,133H-14,133H-15,133H-16,133H-17,133H-18,127S-6,127S-7,127S-8,127S-9,127S-10,127S-11,127S-12,127S-13,127S-14,127S-15,127S-16,127S-17,127S-18,133S-6,133S-7,133S-8,133S-9,133S-10,133S-11,133S-12,133S-13,133S-14,133S-15,133S-16,133S-17,133S-18	34204
Femoral Stem	BB	Ti6Al4V	9#, 10#, 11#, 12#, 13#, 14#, 15#, 16#, 17#, 18#	34204
Acetabular Cup	JS	Ti6Al4V	φ40, φ42, φ44, φ46, φ48, φ50, φ52, φ54, φ56, φ58, φ60, φ62, φ64, φ66, φ68, φ70, φ72	34204
Acetabular Cup	G20	Ti6Al4V	φ40, φ42, φ44, φ46, φ48, φ50, φ52, φ54, φ56, φ58, φ60, φ62, φ64, φ66, φ68, φ70, φ72	34204
Liner	OR	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	15°	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	30°	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	+3	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	+6	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	J10	VE-HXL	φ44, φ46, φ48, φ52, φ56, φ62	33715

Knee Prosthesis - Class III - Sterile

Product Name	Model	Material	Size	GMDN Code
Femoral	XN	Co-Cr-Mo	1#-L/R, 2#-L/R, 2+/-L/R, 3#-L/R, 3+/-L/R, 4#-	32831

Condyle	(PS-WB)		L/R, 4+-L/R, 5#-L/R, 5+-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 9#-L/R, 10#-L/R	
	XN (PS-WTB)	Co-Cr-Mo	1#-L/R, 2#-L/R, 2+-L/R, 3#-L/R, 3+-L/R, 4#-L/R, 4+-L/R, 5#-L/R, 5+-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 9#-L/R, 10#-L/R	32831
	XN (CR)	Co-Cr-Mo	1#-L/R, 2#-L/R, 2+-L/R, 3#-L/R, 3+-L/R, 4#-L/R, 4+-L/R, 5#-L/R, 5+-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 9#-L/R, 10#-L/R	32831
	XN (R)	Co-Cr-Mo	2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R	32831
	XM (PS)	Co-Cr-Mo	2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 10#-L/R	32831
	XM (CR)	Co-Cr-Mo	2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 10#-L/R	32831
	XA	Co-Cr-Mo	1#-L/R, 2#-L/R, 3#-L/R, 3N#-L/R, 4#-L/R, 4N#-L/R, 5#-L/R, 5N#-L/R, 6#-L/R, 6N#-L/R, 7#-L/R, 7N#-L/R, 8#-L/R, 9#-L/R	32831
	KM (PS-WB)	Co-Cr-Mo +TiN	1#-L/R, 2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R	32831
	KM (PS-WTB)	Co-Cr-Mo +TiN	1#-L/R, 2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R	32831
	KM (CR)	Co-Cr-Mo +TiN	1#-L/R, 2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R	32831
	KE	Co-Cr-Mo +TiN	2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R	32831
Tibial Tray	XN	Co-Cr-Mo	1#, 2#, 3#, 4#, 5#, 6#, 7#, 8#, 9#, 10#	32832
	XN (R)	Co-Cr-Mo	2#, 3#, 4#, 5#, 6#, 7#	32832
	XM	Co-Cr-Mo	2#, 3#, 4#, 5#, 6#, 7#, 8#, 10#	32832
	XA	Ti6Al4V +UHMWPE	1#-L/R, 2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 9#-L/R	32832
	KM	Co-Cr-Mo +TiN	1#, 2#, 3#, 4#, 5#, 6#, 7#, 8#	32832
	KE	Co-Cr-Mo +TiN	2#, 3#, 4#, 5#, 6#, 7#	32832
	XN (PS)	UHMWPE / HXLPE /VE-HXL	1#-10, 1#-12, 1#-14, 1#-16, 1#-18, 1#-20; 2/3/3+/4/4+-10, 2/3/3+/4/4+-12, 2/3/3+/4/4+-14, 2/3/3+/4/4+-16, 2/3/3+/4/4+-18, 2/3/3+/4/4+-20; 5/6#-10, 5/6#-12, 5/6#-14, 5/6#-16, 5/6#-18, 5/6#-20; 7/8/9#-10, 7/8/9#-12, 7/8/9#-14, 7/8/9#-16, 7/8/9#-18, 7/8/9#-20; 10#-10, 10#-12, 10#-14, 10#-16, 10#-18, 10#-20	46585
	XN (CR-3°)	UHMWPE / HXLPE	1#-10, 1#-12, 1#-14, 1#-16, 1#-18, 1#-20; 2/3/3+/4/4+-10, 2/3/3+/4/4+-12, 2/3/3+/4/4+-14,	46585

Tibial Insert		/VE-HXL	2/3/3+/4/4+-16, 2/3/3+/4/4+-18, 2/3/3+/4/4+-20; 5/6#-10, 5/6#-12, 5/6#-14, 5/6#-16, 5/6#-18, 5/6#-20; 7/8/9#-10, 7/8/9#-12, 7/8/9#-14, 7/8/9#-16, 7/8/9#-18, 7/8/9#-20; 10#-10, 10#-12, 10#-14, 10#-16, 10#-18, 10#-20	
	XN (CR-DEEP)	UHMWPE / HXLPE /VE-HXL	1#-10, 1#-12, 1#-14, 1#-16, 1#-18, 1#-20; 2/3/3+/4/4+-10, 2/3/3+/4/4+-12, 2/3/3+/4/4+-14, 2/3/3+/4/4+-16, 2/3/3+/4/4+-18, 2/3/3+/4/4+-20; 5/6#-10, 5/6#-12, 5/6#-14, 5/6#-16, 5/6#-18, 5/6#-20; 7/8/9#-10, 7/8/9#-12, 7/8/9#-14, 7/8/9#-16, 7/8/9#-18, 7/8/9#-20; 10#-10, 10#-12, 10#-14, 10#-16, 10#-18, 10#-20;	46585
	XN (R-CCK)	UHMWPE / HXLPE /VE-HXL	2/3/4#-9, 2/3/4#-11, 2/3/4#-13, 2/3/4#-15, 2/3/4#-17, 2/3/4#-19; 5/6#-9, 5/6#-11, 5/6#-13, 5/6#-15, 5/6#-17, 5/6#-19; 7#-9, 7#-11, 7#-13, 7#-15, 7#-17, 7#-19	46585
	XN (R-PSP)	UHMWPE / HXLPE /VE-HXL	2/3/4#-9, 2/3/4#-11, 2/3/4#-13, 2/3/4#-15, 2/3/4#-17, 2/3/4#-19; 5/6#-9, 5/6#-11, 5/6#-13, 5/6#-15, 5/6#-17, 5/6#-19; 7#-9, 7#-11, 7#-13, 7#-15, 7#-17, 7#-19	46585
	XM (PS)	UHMWPE / HXLPE /VE-HXL	2#-9, 2#-11, 2#-13, 2#-15, 2#-17, 2#-19; 3/4#-9, 3/4#-11, 3/4#-13, 3/4#-15, 3/4#-17, 3/4#-19; 5/6#-9, 5/6#-11, 5/6#-13, 5/6#-15, 5/6#-17, 5/6#-19; 7/8#-9, 7/8#-11, 7/8#-13, 7/8#-15, 7/8#-17, 7/8#-19; 10#-9, 10#-11, 10#-13, 10#-15, 10#-17, 10#-19	46585
	XM (CR)	UHMWPE / HXLPE /VE-HXL	2#-9, 2#-11, 2#-13, 2#-15, 2#-17, 2#-19; 3/4#-9, 3/4#-11, 3/4#-13, 3/4#-15, 3/4#-17, 3/4#-19; 5/6#-9, 5/6#-11, 5/6#-13, 5/6#-15, 5/6#-17, 5/6#-19; 7/8#-9, 7/8#-11, 7/8#-13, 7/8#-15, 7/8#-17, 7/8#-19; 10#-9, 10#-11, 10#-13, 10#-15, 10#-17, 10#-19	46585
	XA	UHMWPE / HXLPE /VE-HXL	1#-10, 1#-11, 1#-12, 1#-13, 1#-14, 1#-16, 1#-18; 2#-10, 2#-11, 2#-12, 2#-13, 2#-14, 2#-16, 2#-18; 3#-10, 3#-11, 3#-12, 3#-13, 3#-14, 3#-16, 3#-18; 4#-10, 4#-11, 4#-12, 4#-13, 4#-14, 4#-16, 4#-18; 5#-10, 5#-11, 5#-12, 5#-13, 5#-14, 5#-16, 5#-18; 6#-10, 6#-11, 6#-12, 6#-13, 6#-14, 6#-16, 6#-18; 7#-10, 7#-11, 7#-12, 7#-13, 7#-14, 7#-16, 7#-18; 8#-10, 8#-11, 8#-12, 8#-13, 8#-14, 8#-16, 8#-18; 9#-10, 9#-11, 9#-12, 9#-13, 9#-14, 9#-16, 9#-18	46585
Patella	XN	UHMWPE / HXLPE /VE-HXL	26#-8, 28#-8, 30#-8, 32#-8; 26#-10, 28#-10, 30#-10, 32#-10; 26#-12, 28#-12, 30#-12, 32#-12	34199
	XM	UHMWPE / HXLPE /VE-HXL	26#-8, 29#-8, 32#-8, 35#-8; 26#-10, 29#-10, 32#-10, 35#-10; 26#-12, 29#-12, 32#-12, 35#-12	34199



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	XA (C)	UHMWPE / HXLPE /VE-HXL	26#-8、28#-8、30#-8、32#-8; 26#-10、28#-10、30#-10、32#-10; 26#-12、28#-12、30#-12、32#-12	34199
	XA (O)	UHMWPE / HXLPE /VE-HXL	26#-8、28#-8、30#-8、32#-8; 26#-10、28#-10、30#-10、32#-10; 26#-12、28#-12、30#-12、32#-12	34199
Knee stem	ST	Ti6Al4V	Φ9-60mm、Φ9-100mm、Φ9-130mm、 Φ10-60mm、Φ10-100mm、Φ10-130mm、 Φ11-60mm、Φ11-100mm、Φ11-130mm、 Φ12-60mm、Φ12-100mm、Φ12-130mm、 Φ13-60mm、Φ13-100mm、Φ13-130mm、 Φ14-60mm、Φ14-100mm、Φ14-130mm、 Φ15-60mm、Φ15-100mm、Φ15-130mm、 Φ16-60mm、Φ16-100mm、Φ16-130mm	48066
	OT	Ti6Al4V	Φ9-100mm、Φ9-130mm、Φ10-100mm、Φ10-130mm、 Φ11-100mm、Φ11-130mm、Φ12-100mm、Φ12- 130mm、Φ13-100mm、Φ13-130mm、Φ14-100mm、 Φ14-130mm、Φ15-100mm、Φ15-130mm、Φ16- 100mm、Φ16-130mm	48066

Hip Prosthesis - Class III - Sterile

Product Name	Model	Material	Product Size	GMDN Code
Acetabular Cup	58	Ti6Al4V	φ40, φ42, φ44, φ46, φ48, φ50, φ52, φ54, φ56, φ58, φ60, φ62, φ64, φ66, φ68, φ70, φ72	34204
Bipolar Head	M	CoCrMo	φ38, φ40, φ41, φ42, φ43, φ44, φ45, φ46, φ47, φ48, φ49, φ50, φ51, φ52, φ53, φ54, φ55, φ56, φ57, φ58, φ59, φ60	61786
Femoral Head	T	CoCrMo	22-0, 22-3, 22-6, 22-9, 28-0, 28-3, 28-6, 28-9, 32-(-6), 32-(-3), 32-0, 32-3, 32-6, 32-9, 36-(-6), 36-(-3), 36-0, 36-3, 36-6, 36-9	33181
Liner	58	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	58	HXLPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	JS	Ceramic	28/35, 28/37, 32/39, 36/44, 36/48, 36/52	34204
Femoral Head	TB	Ceramic	36S, 36M, 36L, 32S, 32M, 32L, 32XL, 36XL, 28S, 28M, 28L	34204
Femoral Stem	140	Ti6Al4V	9#, 10#, 11#, 12#, 13#, 14#, 15#	34204
Femoral Stem	BE	Ti6Al4V	8#, 9#, 10#, 11#, 12#, 13#, 14#, 15#, 16#, 17#, 18#	34204
Titanium Screw	6	Ti6Al4V	15mm, 16mm, 17mm, 18mm, 19mm, 20mm, 21mm, 22mm, 23mm, 24mm, 25mm, 26mm, 27mm, 28mm, 29mm, 30mm, 31mm, 32mm, 33mm, 34mm, 35mm, 36mm, 37mm, 38mm, 39mm, 40mm, 41mm, 42mm, 43mm, 44mm, 45mm, 46mm, 47mm, 48mm, 49mm, 50mm, 51mm, 52mm, 53mm, 54mm, 55mm, 56mm, 57mm, 58mm, 59mm, 60mm, 61mm, 62mm, 63mm, 64mm, 65mm, 66mm, 67mm, 68mm, 69mm, 70mm, 71mm, 72mm, 73mm, 74mm, 75mm, 76mm, 77mm, 78mm, 79mm, 80mm	34204
Femoral Stem	130	Ti6Al4V	6#, 7#, 8#, 9#, 10#, 11#, 12#	34204
Femoral Stem	145	Ti6Al4V	7#, 8#, 9#, 10#, 11#, 12#, 13#, 14#	34204



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Femoral Stem	155	Ti6Al4V	8#, 9#, 10#, 11#, 12#, 13#, 14#, 15#, 16#	34204
Femoral Stem	160	Ti6Al4V	150-9,150-10,150-11,150-12,150-13,150-14,150-15,150-16,150-18,150-20	34204
Femoral Stem	BE1	Ti6Al4V	6#, 7#, 8#, 9#, 10#, 11#, 12#, 13#	
Femoral Stem	BE2	Ti6Al4V	127H-6,127H-7,127H-8,127H-9,127H-10,127H-11,127H-12,127H-13,127H-14,127H-15,127H-16,127H-17,127H-18,133H-6,133H-7,133H-8,133H-9,133H-10,133H-11,133H-12,133H-13,133H-14,133H-15,133H-16,133H-17,133H-18,127S-6,127S-7,127S-8,127S-9,127S-10,127S-11,127S-12,127S-13,127S-14,127S-15,127S-16,127S-17,127S-18,133S-6,133S-7,133S-8,133S-9,133S-10,133S-11,133S-12,133S-13,133S-14,133S-15,133S-16,133S-17,133S-18	34204
Femoral Stem	BB	Ti6Al4V	9#, 10#, 11#, 12#, 13#, 14#, 15#, 16#, 17#, 18#	34204
Acetabular Cup	JS	Ti6Al4V	φ40, φ42, φ44, φ46, φ48, φ50, φ52, φ54, φ56, φ58, φ60, φ62, φ64, φ66, φ68, φ70, φ72	34204
Acetabular Cup	G20	Ti6Al4V	φ40, φ42, φ44, φ46, φ48, φ50, φ52, φ54, φ56, φ58, φ60, φ62, φ64, φ66, φ68, φ70, φ72	34204
Liner	OR	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	15°	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	30°	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	+3	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	+6	UHMWPE	φ44, φ46, φ48, φ52, φ56, φ62	33715
Liner	J10	VE-HXL	φ44, φ46, φ48, φ52, φ56, φ62	33715

Knee Prosthesis - Class III - Sterile

Product Name	Model	Material	Size	GMDN Code
Femoral	XN	Co-Cr-Mo	1#-L/R、2#-L/R、2+/-L/R、3#-L/R、3+/-L/R、4#-	32831

Condyle	(PS-WB)		L/R, 4+-L/R, 5#-L/R, 5+-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 9#-L/R, 10#-L/R	
	XN (PS-WTB)	Co-Cr-Mo	1#-L/R, 2#-L/R, 2+-L/R, 3#-L/R, 3+-L/R, 4#-L/R, 4+-L/R, 5#-L/R, 5+-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 9#-L/R, 10#-L/R	32831
	XN (CR)	Co-Cr-Mo	1#-L/R, 2#-L/R, 2+-L/R, 3#-L/R, 3+-L/R, 4#-L/R, 4+-L/R, 5#-L/R, 5+-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 9#-L/R, 10#-L/R	32831
	XN (R)	Co-Cr-Mo	2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R	32831
	XM (PS)	Co-Cr-Mo	2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 10#-L/R	32831
	XM (CR)	Co-Cr-Mo	2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 10#-L/R	32831
	XA	Co-Cr-Mo	1#-L/R, 2#-L/R, 3#-L/R, 3N#-L/R, 4#-L/R, 4N#-L/R, 5#-L/R, 5N#-L/R, 6#-L/R, 6N#-L/R, 7#-L/R, 7N#-L/R, 8#-L/R, 9#-L/R	32831
	KM (PS-WB)	Co-Cr-Mo +TiN	1#-L/R, 2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R	32831
	KM (PS-WTB)	Co-Cr-Mo +TiN	1#-L/R, 2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R	32831
	KM (CR)	Co-Cr-Mo +TiN	1#-L/R, 2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R	32831
	KE	Co-Cr-Mo +TiN	2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R	32831
Tibial Tray	XN	Co-Cr-Mo	1#, 2#, 3#, 4#, 5#, 6#, 7#, 8#, 9#, 10#	32832
	XN (R)	Co-Cr-Mo	2#, 3#, 4#, 5#, 6#, 7#	32832
	XM	Co-Cr-Mo	2#, 3#, 4#, 5#, 6#, 7#, 8#, 10#	32832
	XA	Ti6Al4V +UHMWPE	1#-L/R, 2#-L/R, 3#-L/R, 4#-L/R, 5#-L/R, 6#-L/R, 7#-L/R, 8#-L/R, 9#-L/R	32832
	KM	Co-Cr-Mo +TiN	1#, 2#, 3#, 4#, 5#, 6#, 7#, 8#	32832
	KE	Co-Cr-Mo +TiN	2#, 3#, 4#, 5#, 6#, 7#	32832
	XN (PS)	UHMWPE / HXLPE /VE-HXL	1#-10, 1#-12, 1#-14, 1#-16, 1#-18, 1#-20; 2/3/3+/4/4+-10, 2/3/3+/4/4+-12, 2/3/3+/4/4+-14, 2/3/3+/4/4+-16, 2/3/3+/4/4+-18, 2/3/3+/4/4+-20; 5/6#-10, 5/6#-12, 5/6#-14, 5/6#-16, 5/6#-18, 5/6#-20; 7/8/9#-10, 7/8/9#-12, 7/8/9#-14, 7/8/9#-16, 7/8/9#-18, 7/8/9#-20; 10#-10, 10#-12, 10#-14, 10#-16, 10#-18, 10#-20	46585
	XN (CR-3°)	UHMWPE / HXLPE	1#-10, 1#-12, 1#-14, 1#-16, 1#-18, 1#-20; 2/3/3+/4/4+-10, 2/3/3+/4/4+-12, 2/3/3+/4/4+-14,	46585

Tibial Insert		/VE-HXL	2/3/3+/4/4+-16, 2/3/3+/4/4+-18, 2/3/3+/4/4+-20; 5/6#-10, 5/6#-12, 5/6#-14, 5/6#-16, 5/6#-18, 5/6#-20; 7/8/9#-10, 7/8/9#-12, 7/8/9#-14, 7/8/9#-16, 7/8/9#-18, 7/8/9#-20; 10#-10, 10#-12, 10#-14, 10#-16, 10#-18, 10#-20	
	XN (CR-DEEP)	UHMWPE / HXLPE /VE-HXL	1#-10, 1#-12, 1#-14, 1#-16, 1#-18, 1#-20; 2/3/3+/4/4+-10, 2/3/3+/4/4+-12, 2/3/3+/4/4+-14, 2/3/3+/4/4+-16, 2/3/3+/4/4+-18, 2/3/3+/4/4+-20; 5/6#-10, 5/6#-12, 5/6#-14, 5/6#-16, 5/6#-18, 5/6#-20; 7/8/9#-10, 7/8/9#-12, 7/8/9#-14, 7/8/9#-16, 7/8/9#-18, 7/8/9#-20; 10#-10, 10#-12, 10#-14, 10#-16, 10#-18, 10#-20;	46585
	XN (R-CCK)	UHMWPE / HXLPE /VE-HXL	2/3/4#-9, 2/3/4#-11, 2/3/4#-13, 2/3/4#-15, 2/3/4#-17, 2/3/4#-19; 5/6#-9, 5/6#-11, 5/6#-13, 5/6#-15, 5/6#-17, 5/6#-19; 7#-9, 7#-11, 7#-13, 7#-15, 7#-17, 7#-19	46585
	XN (R-PSP)	UHMWPE / HXLPE /VE-HXL	2/3/4#-9, 2/3/4#-11, 2/3/4#-13, 2/3/4#-15, 2/3/4#-17, 2/3/4#-19; 5/6#-9, 5/6#-11, 5/6#-13, 5/6#-15, 5/6#-17, 5/6#-19; 7#-9, 7#-11, 7#-13, 7#-15, 7#-17, 7#-19	46585
	XM (PS)	UHMWPE / HXLPE /VE-HXL	2#-9, 2#-11, 2#-13, 2#-15, 2#-17, 2#-19; 3/4#-9, 3/4#-11, 3/4#-13, 3/4#-15, 3/4#-17, 3/4#-19; 5/6#-9, 5/6#-11, 5/6#-13, 5/6#-15, 5/6#-17, 5/6#-19; 7/8#-9, 7/8#-11, 7/8#-13, 7/8#-15, 7/8#-17, 7/8#-19; 10#-9, 10#-11, 10#-13, 10#-15, 10#-17, 10#-19	46585
	XM (CR)	UHMWPE / HXLPE /VE-HXL	2#-9, 2#-11, 2#-13, 2#-15, 2#-17, 2#-19; 3/4#-9, 3/4#-11, 3/4#-13, 3/4#-15, 3/4#-17, 3/4#-19; 5/6#-9, 5/6#-11, 5/6#-13, 5/6#-15, 5/6#-17, 5/6#-19; 7/8#-9, 7/8#-11, 7/8#-13, 7/8#-15, 7/8#-17, 7/8#-19; 10#-9, 10#-11, 10#-13, 10#-15, 10#-17, 10#-19	46585
	XA	UHMWPE / HXLPE /VE-HXL	1#-10, 1#-11, 1#-12, 1#-13, 1#-14, 1#-16, 1#-18; 2#-10, 2#-11, 2#-12, 2#-13, 2#-14, 2#-16, 2#-18; 3#-10, 3#-11, 3#-12, 3#-13, 3#-14, 3#-16, 3#-18; 4#-10, 4#-11, 4#-12, 4#-13, 4#-14, 4#-16, 4#-18; 5#-10, 5#-11, 5#-12, 5#-13, 5#-14, 5#-16, 5#-18; 6#-10, 6#-11, 6#-12, 6#-13, 6#-14, 6#-16, 6#-18; 7#-10, 7#-11, 7#-12, 7#-13, 7#-14, 7#-16, 7#-18; 8#-10, 8#-11, 8#-12, 8#-13, 8#-14, 8#-16, 8#-18; 9#-10, 9#-11, 9#-12, 9#-13, 9#-14, 9#-16, 9#-18	46585
Patella	XN	UHMWPE / HXLPE /VE-HXL	26#-8, 28#-8, 30#-8, 32#-8; 26#-10, 28#-10, 30#-10, 32#-10; 26#-12, 28#-12, 30#-12, 32#-12	34199
	XM	UHMWPE / HXLPE /VE-HXL	26#-8, 29#-8, 32#-8, 35#-8; 26#-10, 29#-10, 32#-10, 35#-10; 26#-12, 29#-12, 32#-12, 35#-12	34199



This document containing 5 (five) pages is the Annex of the Certificate with the revision number 02, with the number M.2020.106.13652 and with the registration date of 23.06.2020 and with the revision date of 25.05.2021 issued for "Beijing Chunlizhengda Medical Instruments Co., Ltd." 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.

	XA (C)	UHMWPE / HXLPE /VE-HXL	26#-8、28#-8、30#-8、32#-8; 26#-10、28#-10、30#-10、32#-10; 26#-12、28#-12、30#-12、32#-12	34199
	XA (O)	UHMWPE / HXLPE /VE-HXL	26#-8、28#-8、30#-8、32#-8; 26#-10、28#-10、30#-10、32#-10; 26#-12、28#-12、30#-12、32#-12	34199
Knee stem	ST	Ti6Al4V	Φ9-60mm、Φ9-100mm、Φ9-130mm、 Φ10-60mm、Φ10-100mm、Φ10-130mm、 Φ11-60mm、Φ11-100mm、Φ11-130mm、 Φ12-60mm、Φ12-100mm、Φ12-130mm、 Φ13-60mm、Φ13-100mm、Φ13-130mm、 Φ14-60mm、Φ14-100mm、Φ14-130mm、 Φ15-60mm、Φ15-100mm、Φ15-130mm、 Φ16-60mm、Φ16-100mm、Φ16-130mm	48066
	OT	Ti6Al4V	Φ9-100mm、Φ9-130mm、Φ10-100mm、Φ10-130mm、 Φ11-100mm、Φ11-130mm、Φ12-100mm、Φ12- 130mm、Φ13-100mm、Φ13-130mm、Φ14-100mm、 Φ14-130mm、Φ15-100mm、Φ15-130mm、Φ16- 100mm、Φ16-130mm	48066