



EC DESIGN EXAMINATION CERTIFICATE

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

With the expire of the certificate M.2021.106.14551 the validity of the certificate
M.2021.106.14551-1 will also end.

Company Name : Beijing LiDaKang Technology Co., Ltd.

Company Address : East District, building 5, No. 19, Dongying Road, Zhaofeng Industrial
Base, Zhaoquanying Town, Shunyi District, Beijing China

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

Product : Sterile (R), Primer Knee Prosthesis, Class III
Sterile (R), Revision Knee Prosthesis, Class III

GMDN : 32831, 32832, 33665, 34199, 46585, 46646, 32841, 48067, 61560

Product Types are attached.

Certificate Number : M.2021.106.14551-1

Report Number : MD.4054.IB

Initial Assessment Date : 23.03.2021

Registration Date : 17.05.2021

Revision Date /No : -

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.

Address: Mutlukent 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 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

Product List of Primer Knee Prosthesis

No:1 Series

No	Product Name	Model	Specification	Reference No	Material
1	Knee prosthesis -femoral condyle	RY A201	1L	50111P	CoCrMo
			2L	50112P	CoCrMo
			3L	50113P	CoCrMo
			4L	50114P	CoCrMo
			5L	50115P	CoCrMo
			6L	50121P	CoCrMo
			1R	50116P	CoCrMo
			2R	50117P	CoCrMo
			3R	50118P	CoCrMo
			4R	50119P	CoCrMo
			5R	50120P	CoCrMo
			6R	50122P	CoCrMo
2	Knee prosthesis -tibial Tray	RY B401	1#	50126	CoCrMo
			2#	50127	CoCrMo
			3#	50128	CoCrMo
			4#	50129	CoCrMo
			5#	50130	CoCrMo
			6#	50131	CoCrMo
3	Knee prosthesis -tibial insert	RY C401	1#/9mm	50136P-9	PE
			1#/11mm	50136P-11	PE
			1#/13mm	50136P-13	PE
			1#/15mm	50136P-15	PE
			2#/9mm	50137P-9	PE
			2#/11mm	50137P-11	PE
			2#/13mm	50137P-13	PE
			2#/15mm	50137P-15	PE
			3#/9mm	50138P-9	PE
			3#/11mm	50138P-11	PE
			3#/13mm	50138P-13	PE
			3#/15mm	50138P-15	PE
			4#/9mm	50139P-9	PE
			4#/11mm	50139P-11	PE
			4#/13mm	50139P-13	PE
			4#/15mm	50139P-15	PE
			5#/9mm	50140P-9	PE
			5#/11mm	50140P-11	PE
			5#/13mm	50140P-13	PE
			5#/15mm	50140P-15	PE
6#/9mm	50141P-9	PE			
6#/11mm	50141P-11	PE			
6#/13mm	50141P-13	PE			
6#/15mm	50141P-15	PE			
4	Knee prosthesis -patell	RY D01	1#	50144B-8	PE
			2#	50145B-8	PE
			3#	50147B-8	PE
			4#8mm	50141B-8	PE
			4#10mm	50141B-10	PE
			5#	50146B-8	PE
			6#8mm	50142B-8	PE
			6#10mm	50142B-10	PE
			7#	50148B-8	PE
			8#	50143B-10	PE
9#	50149B-10	PE			



This document containing 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

Accessories

No	Product Name	Model	Specification	Reference No	Material	Packed Products
5	locking nail	XR J01	15mm	50161-15	TC4	RY B401

No:2 Series

No	Product Name	Model	Specification	Reference No	Material
1	Knee prosthesis -femoral condyle	RY A203	1#L	A5100-01L	CoCrMo
			2#L	A5100-02L	CoCrMo
			3#L	A5100-03L	CoCrMo
			4#L	A5100-04L	CoCrMo
			5#L	A5100-05L	CoCrMo
			6#L	A5100-06L	CoCrMo
			7#L	A5100-07L	CoCrMo
			1#R	A5100-01R	CoCrMo
			2#R	A5100-02R	CoCrMo
			3#R	A5100-03R	CoCrMo
			4#R	A5100-04R	CoCrMo
			5#R	A5100-05R	CoCrMo
			6#R	A5100-06R	CoCrMo
			7#R	A5100-07R	CoCrMo
			M2#L	A5100-M2L	CoCrMo
			M3#L	A5100-M3L	CoCrMo
			M4#L	A5100-M4L	CoCrMo
			M5#L	A5100-M5L	CoCrMo
			M2#R	A5100-M2R	CoCrMo
			M3#R	A5100-M3R	CoCrMo
M4#R	A5100-M4R	CoCrMo			
M5#R	A5100-M5R	CoCrMo			
2	Knee prosthesis- tibial Tray	RY B403	M1#L	A5200-M1L	CoCrMo
			1#L	A5200-01L	CoCrMo
			M2#L	A5200-M2L	CoCrMo
			2#L	A5200-02L	CoCrMo
			M3#L	A5200-M3L	CoCrMo
			3#L	A5200-03L	CoCrMo
			M4#L	A5200-M4L	CoCrMo
			4#L	A5200-04L	CoCrMo
			M5#L	A5200-M5L	CoCrMo
			5#L	A5200-05L	CoCrMo
			M6#L	A5200-M6L	CoCrMo
			6#L	A5200-06L	CoCrMo
			M7#L	A5200-M7L	CoCrMo
			7#L	A5200-07L	CoCrMo
			M1#R	A5200-M1R	CoCrMo
			1#R	A5200-01R	CoCrMo
			M2#R	A5200-M2R	CoCrMo
			2#R	A5200-02R	CoCrMo
			M3#R	A5200-M3R	CoCrMo
			3#R	A5200-03R	CoCrMo
M4#R	A5200-M4R	CoCrMo			
4#R	A5200-04R	CoCrMo			
M5#R	A5200-M5R	CoCrMo			
5#R	A5200-05R	CoCrMo			
M6#R	A5200-M6R	CoCrMo			
6#R	A5200-06R	CoCrMo			
M7#R	A5200-M7R	CoCrMo			
7#R	A5200-07R	CoCrMo			
			M1#-9mmL	A5300-0109L	PE
			M1#-11mmL	A5300-0111L	PE
			M1#-13mmL	A5300-0113L	PE
			M1#-15mmL	A5300-0115L	PE
			M2#-9mmL	A5300-0209L	PE



This document containing 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

3	Knee prosthesis -tibial insert	RY C403	M2#-11mmL	A5300-0211L	PE
			M2#-13mmL	A5300-0213L	PE
			M2#-15mmL	A5300-0215L	PE
			M3#-9mmL	A5300-0309L	PE
			M3#-11mmL	A5300-0311L	PE
			M3#-13mmL	A5300-0313L	PE
			M3#-15mmL	A5300-0315L	PE
			M4#-9mmL	A5300-0409L	PE
			M4#-11mmL	A5300-0411L	PE
			M4#-13mmL	A5300-0413L	PE
			M4#-15mmL	A5300-0415L	PE
			M5#-9mmL	A5300-0509L	PE
			M5#-11mmL	A5300-0511L	PE
			M5#-13mmL	A5300-0513L	PE
			M5#-15mmL	A5300-0515L	PE
			M6#-9mmL	A5300-0609L	PE
			M6#-11mmL	A5300-0611L	PE
			M6#-13mmL	A5300-0613L	PE
			M6#-15mmL	A5300-0615L	PE
			M7#-9mmL	A5300-0709L	PE
			M7#-11mmL	A5300-0711L	PE
			M7#-13mmL	A5300-0713L	PE
			M7#-15mmL	A5300-0715L	PE
			M1#-9mmR	A5300-0109R	PE
			M1#-11mmR	A5300-0111R	PE
			M1#-13mmR	A5300-0113R	PE
			M1#-15mmR	A5300-0115R	PE
			M2#-9mmR	A5300-0209R	PE
			M2#-11mmR	A5300-0211R	PE
			M2#-13mmR	A5300-0213R	PE
			M2#-15mmR	A5300-0215R	PE
			M3#-9mmR	A5300-0309R	PE
			M3#-11mmR	A5300-0311R	PE
			M3#-13mmR	A5300-0313R	PE
			M3#-15mmR	A5300-0315R	PE
			M4#-9mmR	A5300-0409R	PE
			M4#-11mmR	A5300-0411R	PE
			M4#-13mmR	A5300-0413R	PE
			M4#-15mmR	A5300-0415R	PE
			M5#-9mmR	A5300-0509R	PE
M5#-11mmR	A5300-0511R	PE			
M5#-13mmR	A5300-0513R	PE			
M5#-15mmR	A5300-0515R	PE			
M6#-9mmR	A5300-0609R	PE			
M6#-11mmR	A5300-0611R	PE			
M6#-13mmR	A5300-0613R	PE			
M6#-15mmR	A5300-0615R	PE			
M7#-9mmR	A5300-0709R	PE			
M7#-11mmR	A5300-0711R	PE			
M7#-13mmR	A5300-0713R	PE			
M7#-15mmR	A5300-0715R	PE			

No:5 Series

No	Product Name	Model	Specification	Reference No	Material
1	Knee prosthesis- femoral condyle	DK 01	1#LM/RL	A5101-01LM	CoCrMo
			2#LM/RL	A5101-02LM	CoCrMo
			3#LM/RL	A5101-03LM	CoCrMo
			4#LM/RL	A5101-04LM	CoCrMo
			5#LM/RL	A5101-05LM	CoCrMo
			6#LM/RL	A5101-06LM	CoCrMo
			1#RM/LL	A5101-01RM	CoCrMo



This document containing 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

			2#RM/LL	A5101-02RM	CoCrMo			
			3#RM/LL	A5101-03RM	CoCrMo			
			4#RM/LL	A5101-04RM	CoCrMo			
			5#RM/LL	A5101-05RM	CoCrMo			
			6#RM/LL	A5101-06RM	CoCrMo			
			1#	A5101-01	CoCrMo			
			2#	A5101-02	CoCrMo			
			3#	A5101-03	CoCrMo			
			4#	A5101-04	CoCrMo			
			5#	A5101-05	CoCrMo			
			6#	A5105-06	CoCrMo			
			2	Knee prosthesis- tibial tray	DT 01	S1#LM	A5201-S1L	CoCrMo
						1#LM	A5201-01L	CoCrMo
						2#LM	A5201-02L	CoCrMo
3#LM	A5201-03L	CoCrMo						
4#LM	A5201-04L	CoCrMo						
5#LM	A5201-05L	CoCrMo						
S1#RM	A5201-S1R	CoCrMo						
1#RM	A5201-01R	CoCrMo						
2#RM	A5201-02R	CoCrMo						
3#RM	A5201-03R	CoCrMo						
4#RM	A5201-04R	CoCrMo						
5#RM	A5201-05R	CoCrMo						
S1#LM/RL	A5201-S1LM	CoCrMo						
1#LM/RL	A5201-01LM	CoCrMo						
2#LM/RL	A5201-02LM	CoCrMo						
3#LM/RL	A5201-03LM	CoCrMo						
4#LM/RL	A5201-04LM	CoCrMo						
5#LM/RL	A5201-05LM	CoCrMo						
S1#RM/LL	A5201-S1RM	CoCrMo						
1#RM/LL	A5201-01RM	CoCrMo						
2#RM/LL	A5201-02RM	CoCrMo						
3#RM/LL	A5201-03RM	CoCrMo						
4#RM/LL	A5201-04RM	CoCrMo						
5#RM/LL	A5201-05RM	CoCrMo						
3	Knee prosthesis- tibial insert	DD 01				S1#-6mm	A5301-S106	PE
						S1#-7mm	A5301-S107	PE
						S1#-8mm	A5301-S108	PE
						S1#-9mm	A5301-S109	PE
			S1#-10mm	A5301-S110	PE			
			S1#-11mm	A5301-S111	PE			
			S1#-12mm	A5301-S112	PE			
			S1#-14mm	A5301-S114	PE			
			1#-6mm	A5301-0106	PE			
			1#-7mm	A5301-0107	PE			
			1#-8mm	A5301-0108	PE			
			1#-9mm	A5301-0109	PE			
			1#-10mm	A5301-0110	PE			
			1#-11mm	A5301-0111	PE			
			1#-12mm	A5301-0112	PE			
			1#-14mm	A5301-0114	PE			
			2#-6mm	A5301-0206	PE			
			2#-7mm	A5301-0207	PE			
			2#-8mm	A5301-0208	PE			
			2#-9mm	A5301-0209	PE			
			2#-10mm	A5301-0210	PE			
			2#-11mm	A5301-0211	PE			
			2#-12mm	A5301-0212	PE			
			2#-14mm	A5301-0214	PE			
			3#-6mm	A5301-0306	PE			
			3#-7mm	A5301-0307	PE			



This document containing 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

			3#-8mm	A5301-0308	PE
			3#-9mm	A5301-0309	PE
			3#-10mm	A5301-0310	PE
			3#-11mm	A5301-0311	PE
			3#-12mm	A5301-0312	PE
			3#-14mm	A5301-0314	PE
			4#-6mm	A5301-0406	PE
			4#-7mm	A5301-0407	PE
			4#-8mm	A5301-0408	PE
			4#-9mm	A5301-0409	PE
			4#-10mm	A5301-0410	PE
			4#-11mm	A5301-0411	PE
			4#-12mm	A5301-0412	PE
			4#-14mm	A5301-0414	PE
			5#-6mm	A5301-0506	PE
			5#-7mm	A5301-0507	PE
			5#-8mm	A5301-0508	PE
			5#-9mm	A5301-0509	PE
			5#-10mm	A5301-0510	PE
			5#-11mm	A5301-0511	PE
			5#-12mm	A5301-0512	PE
			5#-14mm	A5301-0514	PE
			S1#-6mmLM/RL	A5301-S106LM	PE
			S1#-7mmLM/RL	A5301-S107LM	PE
			S1#-8mmLM/RL	A5301-S108LM	PE
			S1#-9mmLM/RL	A5301-S109LM	PE
			S1#-10mmLM/RL	A5301-S110LM	PE
			S1#-11mmLM/RL	A5301-S111LM	PE
			S1#-12mmLM/RL	A5301-S112LM	PE
			S1#-14mmLM/RL	A5301-S114LM	PE
			1#-6mmLM/RL	A5301-0106LM	PE
			1#-7mmLM/RL	A5301-0107LM	PE
			1#-8mmLM/RL	A5301-0108LM	PE
			1#-9mmLM/RL	A5301-0109LM	PE
			1#-10mmLM/RL	A5301-0110LM	PE
			1#-11mmLM/RL	A5301-0111LM	PE
			1#-12mmLM/RL	A5301-0112LM	PE
			1#-14mmLM/RL	A5301-0114LM	PE
			2#-6mmLM/RL	A5301-0206LM	PE
			2#-7mmLM/RL	A5301-0207LM	PE
			2#-8mmLM/RL	A5301-0208LM	PE
			2#-9mmLM/RL	A5301-0209LM	PE
			2#-10mmLM/RL	A5301-0210LM	PE
			2#-11mmLM/RL	A5301-0211LM	PE
			2#-12mmLM/RL	A5301-0212LM	PE
			2#-14mmLM/RL	A5301-0214LM	PE
			3#-6mmLM/RL	A5301-0306LM	PE
			3#-7mmLM/RL	A5301-0307LM	PE
			3#-8mmLM/RL	A5301-0308LM	PE
			3#-9mmLM/RL	A5301-0309LM	PE
			3#-10mmLM/RL	A5301-0310LM	PE
			3#-11mmLM/RL	A5301-0311LM	PE
			3#-12mmLM/RL	A5301-0312LM	PE
			3#-14mmLM/RL	A5301-0314LM	PE
			4#-6mmLM/RL	A5301-0406LM	PE
			4#-7mmLM/RL	A5301-0407LM	PE
			4#-8mmLM/RL	A5301-0408LM	PE
			4#-9mmLM/RL	A5301-0409LM	PE
			4#-10mmLM/RL	A5301-0410LM	PE
			4#-11mmLM/RL	A5301-0411LM	PE
			4#-12mmLM/RL	A5301-0412LM	PE



This document containing 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

			4#-14mmLM/RL	A5301-0414LM	PE
			5#-6mmLM/RL	A5301-0506LM	PE
			5#-7mmLM/RL	A5301-0507LM	PE
			5#-8mmLM/RL	A5301-0508LM	PE
			5#-9mmLM/RL	A5301-0509LM	PE
			5#-10mmLM/RL	A5301-0510LM	PE
			5#-11mmLM/RL	A5301-0511LM	PE
			5#-12mmLM/RL	A5301-0512LM	PE
			5#-14mmLM/RL	A5301-0514LM	PE
			S1#-6mmRM/LL	A5301-S106RM	PE
			S1#-7mmRM/LL	A5301-S107RM	PE
			S1#-8mmRM/LL	A5301-S108RM	PE
			S1#-9mmRM/LL	A5301-S109RM	PE
			S1#-10mmRM/LL	A5301-S110RM	PE
			S1#-11mmRM/LL	A5301-S111RM	PE
			S1#-12mmRM/LL	A5301-S112RM	PE
			S1#-14mmRM/LL	A5301-S114RM	PE
			1#-6mmRM/LL	A5301-0106RM	PE
			1#-7mmRM/LL	A5301-0107RM	PE
			1#-8mmRM/LL	A5301-0108RM	PE
			1#-9mmRM/LL	A5301-0109RM	PE
			1#-10mmRM/LL	A5301-0110RM	PE
			1#-11mmRM/LL	A5301-0111RM	PE
			1#-12mmRM/LL	A5301-0112RM	PE
			1#-14mmRM/LL	A5301-0114RM	PE
			2#-6mmRM/LL	A5301-0206RM	PE
			2#-7mmRM/LL	A5301-0207RM	PE
			2#-8mmRM/LL	A5301-0208RM	PE
			2#-9mmRM/LL	A5301-0209RM	PE
			2#-10mmRM/LL	A5301-0210RM	PE
			2#-11mmRM/LL	A5301-0211RM	PE
			2#-12mmRM/LL	A5301-0212RM	PE
			2#-14mmRM/LL	A5301-0214RM	PE
			3#-6mmRM/LL	A5301-0306RM	PE
			3#-7mmRM/LL	A5301-0307RM	PE
			3#-8mmRM/LL	A5301-0308RM	PE
			3#-9mmRM/LL	A5301-0309RM	PE
			3#-10mmRM/LL	A5301-0310RM	PE
			3#-11mmRM/LL	A5301-0311RM	PE
			3#-12mmRM/LL	A5301-0312RM	PE
			3#-14mmRM/LL	A5301-0314RM	PE
			4#-6mmRM/LL	A5301-0406RM	PE
			4#-7mmRM/LL	A5301-0407RM	PE
			4#-8mmRM/LL	A5301-0408RM	PE
			4#-9mmRM/LL	A5301-0409RM	PE
			4#-10mmRM/LL	A5301-0410RM	PE
			4#-11mmRM/LL	A5301-0411RM	PE
			4#-12mmRM/LL	A5301-0412RM	PE
			4#-14mmRM/LL	A5301-0414RM	PE
			5#-6mmRM/LL	A5301-0506RM	PE
			5#-7mmRM/LL	A5301-0507RM	PE
			5#-8mmRM/LL	A5301-0508RM	PE
			5#-9mmRM/LL	A5301-0509RM	PE
			5#-10mmRM/LL	A5301-0510RM	PE
			5#-11mmRM/LL	A5301-0511RM	PE
			5#-12mmRM/LL	A5301-0512RM	PE
			5#-14mmRM/LL	A5301-0514RM	PE



This document containing 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

Product List of Revision Knee Prosthesis

No:3 Series

No	Product Name	Model	Specification	Material	Reference No
1	Knee prosthesis- femoral condyle	XR A301	1L	CoCrMo	51501-1
			2L	CoCrMo	51501-2
			3L	CoCrMo	51501-5
			4L	CoCrMo	51501-6
			5L	CoCrMo	51501-7
			1R	CoCrMo	51501-3
			2R	CoCrMo	51501-4
			3R	CoCrMo	51501-8
			4R	CoCrMo	51501-9
			5R	CoCrMo	51501-10
2	Knee prosthesis- femoral condyle	XR A302	1L	CoCrMo	51401-1
			2L	CoCrMo	51401-2
			3L	CoCrMo	51401-3
			4L	CoCrMo	51401-7
			5L	CoCrMo	51401-8
			1R	CoCrMo	51401-4
			2R	CoCrMo	51401-5
			3R	CoCrMo	51401-6
			4R	CoCrMo	51401-9
			5R	CoCrMo	51401-10
3	Knee prosthesis- tibial tray	XR B301	1#	CoCrMo	51402-1
			2#	CoCrMo	51402-2
			3#	CoCrMo	51402-3
			4#	CoCrMo	51402-4
			5#	CoCrMo	51402-5
4	Knee prosthesis- tibial tray	XR B302	1#	CoCrMo	51502-1
			2#	CoCrMo	51502-2
			3#	CoCrMo	51502-3
			4#	CoCrMo	51502-4
			5#	CoCrMo	51502-5
			M1#	CoCrMo	51506-1
			M2#	CoCrMo	51506-2
			M3#	CoCrMo	51506-3
			M4#	CoCrMo	51506-4
			M5#	CoCrMo	51506-5
5	Knee prosthesis- tibial insert	XR C301	1#/11mm	PE	51405-1-11
			1#/13mm	PE	51405-1-13
			1#/16mm	PE	51405-1-16
			1#/20mm	PE	51405-1-20
			2#/11mm	PE	51405-2-11
			2#/13mm	PE	51405-2-13
			2#/16mm	PE	51405-2-16
			2#/20mm	PE	51405-2-20
			3#/11mm	PE	51405-3-11
			3#/13mm	PE	51405-3-13
			3#/16mm	PE	51405-3-16
			3#/20mm	PE	51405-3-20
			4#/11mm	PE	51405-4-11
			4#/13mm	PE	51405-4-13
			4#/16mm	PE	51405-4-16
			4#/20mm	PE	51405-4-20
			5#/11mm	PE	51405-5-11
5#/13mm	PE	51405-5-13			
5#/16mm	PE	51405-5-16			
5#/20mm	PE	51405-5-20			



This document containing 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

6	Knee prosthesis- shaft pin	XR G02	φ10x52	CoCrMo	51407-52
			φ10x64	CoCrMo	51407-64
7	Knee prosthesis- carden shaft	XR F01	51mm	CoCrMo	51404-51
			61mm	CoCrMo	51404-61
8	Knee prosthesis - medullary cavity extension handle	XR D01	φ9x110	TC4	51503-01
			φ10x125	TC4	51503-02
			φ11x120	TC4	51503-03
			φ12x150	TC4	51503-04
			φ13x150	TC4	51503-05
			φ14x150	TC4	51503-06
			φ11x150	TC4	51503-07
			φ12x120	TC4	51503-08
9	Knee prosthesis - medullary cavity extension handle	XR D02	φ10x90	TC4	51409-01
			φ11x100	TC4	51409-02
			φ12x110	TC4	51409-03
			φ13x120	TC4	51409-04
10	Knee prosthesis - medullary cavity extension handle	XR D03	φ9x110	TC4	51505-01
			φ10x125	TC4	51505-02
			φ11x120	TC4	51505-03
			φ12x150	TC4	51505-04
			φ13x150	TC4	51505-05
			φ14x150	TC4	51505-06
			φ11x180	TC4	51505-07
			φ12x180	TC4	51505-08
			φ13x180	TC4	51505-09
			φ14x180	TC4	51505-10
			φ11x150	TC4	51505-11
			φ12x120	TC4	51505-12
11	Knee prosthesis - backbone extension segment	XR M01	30mm	CoCrMo	51504-030
			40mm	TC4	51504-040
			50mm	TC4	51504-050
			60mm	TC4	51504-060
			70mm	TC4	51504-070
			80mm	TC4	51504-080
			100mm	TC4	51504-100
			120mm	TC4	51504-120
			140mm	TC4	51504-140
			160mm	TC4	51504-160
			180mm	TC4	51504-180
			200mm	TC4	51504-200
12	Knee prosthesis - backbone extension segment	XR M02	80mm(L)	TC4	51802-080L
			80mm(R)	TC4	51802-080R
			90mm(L)	TC4	51803-090L
			90mm(R)	TC4	51803-090R

Accessories

No	Product Name	Model	Specification	Material	Reference No	Packed Products
13	locking pad	XR H01	22mm	PE	51403-22	XR F01
14	liner/gasket	XR I01	Diameter:16mm Length:16mm	PE	51408-16	XR A301
			Diameter:16mm Length:21mm	PE	51408-21	XR A302
15	sleeve	XR E01	39mm	PE	51406-39	XR B301 XR B302



This document containing 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

No:4 Series

No	Product Name	Model	Specification	Reference No	Material
1	Knee prosthesis- femoral condyle	RY A202	1L	52001-1L	CoCrMo
			2L	52001-2L	CoCrMo
			3L	52001-3L	CoCrMo
			4L	52001-4L	CoCrMo
			5L	52001-5L	CoCrMo
			6L	52001-6L	CoCrMo
			1R	52001-1R	CoCrMo
			2R	52001-2R	CoCrMo
			3R	52001-3R	CoCrMo
			4R	52001-4R	CoCrMo
			5R	52001-5R	CoCrMo
			6R	52001-6R	CoCrMo
2	Knee prosthesis tibial tray	RY B402	1#	52002-1	CoCrMo
			2#	52002-2	CoCrMo
			3#	52002-3	CoCrMo
			4#	52002-4	CoCrMo
			5#	52002-5	CoCrMo
			6#	52002-6	CoCrMo
3	Knee prosthesis tibial insert	RY C402	1#/9mm	52003-1-9	PE
			1#/11mm	52003-1-11	PE
			1#/13mm	52003-1-13	PE
			1#/15mm	52003-1-15	PE
			1#/18mm	52003-1-18	PE
			1#/21mm	52003-1-21	PE
			2#/9mm	52003-2-9	PE
			2#/11mm	52003-2-11	PE
			2#/13mm	52003-2-13	PE
			2#/15mm	52003-2-15	PE
			2#/18mm	52003-2-18	PE
			2#/21mm	52003-2-21	PE
			3#/9mm	52003-3-9	PE
			3#/11mm	52003-3-11	PE
			3#/13mm	52003-3-13	PE
			3#/15mm	52003-3-15	PE
			3#/18mm	52003-3-18	PE
			3#/21mm	52003-3-21	PE
			4#/9mm	52003-4-9	PE
			4#/11mm	52003-4-11	PE
			4#/13mm	52003-4-13	PE
			4#/15mm	52003-4-15	PE
			4#/18mm	52003-4-18	PE
			4#/21mm	52003-4-21	PE
			5#/9mm	52003-5-9	PE
			5#/11mm	52003-5-11	PE
			5#/13mm	52003-5-13	PE
			5#/15mm	52003-5-15	PE
			5#/18mm	52003-5-18	PE
			5#/21mm	52003-5-21	PE
6#/9mm	52003-6-9	PE			
6#/11mm	52003-6-11	PE			
6#/13mm	52003-6-13	PE			
6#/15mm	52003-6-15	PE			
6#/18mm	52003-6-18	PE			
6#/21mm	52003-6-21	PE			
4	Knee prosthesis - medullary cavity extension handle	XR D05	Φ10×80mm	52004-10-80	TC4
			Φ12×80mm	52004-12-80	TC4
			Φ14×80mm	52004-14-80	TC4
			Φ16×80mm	52004-16-80	TC4
			Φ18×80mm	52004-18-80	TC4



This document containing 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

			Φ10×120mm	52004-10-120	TC4			
			Φ12×120mm	52004-12-120	TC4			
			Φ14×120mm	52004-14-120	TC4			
			Φ16×120mm	52004-16-120	TC4			
			Φ18×120mm	52004-18-120	TC4			
			Φ15×30mm	52010-15-30	TC4			
5	Knee prosthesis support block	XR K02	1#/5mm	52005-1-5	TC4			
			2#/5mm	52005-2-5	TC4			
			3#/5mm	52005-3-5	TC4			
			4#/5mm	52005-4-5	TC4			
			5#/5mm	52005-5-5	TC4			
			6#/5mm	52005-6-5	TC4			
			1#/10mm	52005-1-10	TC4			
			2#/10mm	52005-2-10	TC4			
			3#/10mm	52005-3-10	TC4			
			4#/10mm	52005-4-10	TC4			
			5#/10mm	52005-5-10	TC4			
			6#/10mm	52005-6-10	TC4			
			6	Knee prosthesis support block	XR K01	1#/5mm	52006-1-5	TC4
						2#/5mm	52006-2-5	TC4
3#/5mm	52006-3-5	TC4						
4#/5mm	52006-4-5	TC4						
5#/5mm	52006-5-5	TC4						
6#/5mm	52006-6-5	TC4						
1#/10mm	52006-1-10	TC4						
2#/10mm	52006-2-10	TC4						
3#/10mm	52006-3-10	TC4						
4#/10mm	52006-4-10	TC4						
5#/10mm	52006-5-10	TC4						
6#/10mm	52006-6-10	TC4						
7	gasket/linear	XR L01				1L/5mm	52007-1L-5	TC4
						2L/5mm	52007-2L-5	TC4
			3L/5mm	52007-3L-5	TC4			
			4L/5mm	52007-4L-5	TC4			
			5L/5mm	52007-5L-5	TC4			
			6L/5mm	52007-6L-5	TC4			
			1L/10mm	52007-1L-10	TC4			
			2L/10mm	52007-2L-10	TC4			
			3L/10mm	52007-3L-10	TC4			
			4L/10mm	52007-4L-10	TC4			
			5L/10mm	52007-5L-10	TC4			
			6L/10mm	52007-6L-10	TC4			
			1R/5mm	52007-1R-5	TC4			
			2R/5mm	52007-2R-5	TC4			
			3R/5mm	52007-3R-5	TC4			
			4R/5mm	52007-4R-5	TC4			
			5R/5mm	52007-5R-5	TC4			
			6R/5mm	52007-6R-5	TC4			
			1R/10mm	52007-1R-10	TC4			
			2R/10mm	52007-2R-10	TC4			
			3R/10mm	52007-3R-10	TC4			
			4R/10mm	52007-4R-10	TC4			
5R/10mm	52007-5R-10	TC4						
6R/10mm	52007-6R-10	TC4						
8	Knee prosthesis backbone extension segment	XR M03	30mm	52008-2	TC4			
			40mm	52008-4	TC4			
			50mm	52008-6	TC4			



This document containing 11 (eleven) pages is the Annex of the Certificate with the number M.2021.106.14551-1 and with the registration date of 17.05.2021 issued for “Beijing LiDaKang Technology 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.

Accessories

No	Product Name	Model	Specification	Reference No	Material	Packed Products
9	locking nail	XR J03	6mm	52009	TC4	XR L01
			12mm	52009-8	TC4	XR K01 XR K02
10	locking nail	XR J04	5mm	52010	TC4	RY A202 RY B402 XR M03
11	locking nail	XR J01	15mm	50161-15	TC4	RY B402



CERTIFICATE

EC Design-Examination Certificate

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

With the expire of the certificate M.2020.106.13592 the validity of the certificate M.2020.106.13592-1 will also end.

Company Name : Beijing LiDaKang Technology Co.,Ltd.

Company Address : Eastern District of Building 5, No. 19, Dongying Road, Zhaofeng Industrial Base, Zhaoquanying Town, Shunyi District, Beijing, China

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

Product : Sterile, Hip Joint Prostheses - Class III

GMDN : 34191, 60516, 43168, 38156, 33175

Product Types are attached.

Certificate Number : M.2020.106.13592-1
Report Number : MD.4054.IB
Initial Assessment Date : 18.12.2019
Registration Date : 02.06.2020
Revision Date /No : -
Expiry Date : 27.05.2024



The EC desing 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.

Address: Mutlukent 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 1 (one) pages is the Annex of the Certificate with the number M.2020.106. 13592-1 and with the registration date of 02.06.2020 issued for "Beijing LiDaKang Technology 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.

4

Hip Joint Prostheses – ClassIII -Sterile			
Femoral Stem			
Product Name	GMDN Code	Product model	Product Size
Femoral Stem (Tantalum coating)	34191	JX 111	1#, 2#, 3#, 4#, 5#, 6#, 7#, 8#, 9#, 10#, 11#, 12#
		JX 112	1#, 2#, 3#, 4#, 5#, 6#, 7#, 8#, 9#, 10#, 11#, 12#
		JX 114	1#, 2#, 3#, 4#, 5#, 6#, 7#, 8#, 9#, 10#, 11#, 12#
Femoral stem (Titanium coating)	34191	JX F1104	1#, 2#, 3#, 4#, 5#, 6#, 7#, 8#, 9#, 10#, 11#, 12#
		JX F1106	1#, 2#, 3#, 4#, 5#, 6#, 7#, 8#, 9#, 10#, 11#, 12#
		JX T1102	1#, 2#, 3#, 4#, 5#, 6#, 7#, 8#, 9#, 10#, 11#, 12#
Acetabular Cup			
Product Name	GMDN Code	Product model	Product Size
Acetabular Cup	60516	JX 220	36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76
		JX 221	36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76
		JX 222	36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76
Titanium nail	60516	JX 6301	φ5.0*15, φ5.0*20, φ5.0*25, φ5.0*30, φ5.0*35, φ5.0*40, φ5.0*45, φ5.0*50 φ5.5*15, φ5.5*20, φ5.5*25, φ5.5*30, φ5.5*35, φ5.5*40, φ5.5*45, φ5.5*50 φ6.0*15, φ6.0*20, φ6.0*25, φ6.0*30, φ6.0*35, φ6.0*40, φ6.0*45, φ6.0*50 φ6.5*15, φ6.5*20, φ6.5*25, φ6.5*30, φ6.5*35, φ6.5*40, φ6.5*45, φ6.5*50
VE liner			
Product Name	GMDN Code	Product model	Product Size
VE liner	43168	JX 320	36/22, 38/22, 40/22, 42/22, 44/28, 46/28, 46/32, 48/28, 48/32, 50/28, 50/32, 52/28, 52/32, 52/36, 54/28, 54/32, 54/36, 56/28, 56/32, 56/36, 58/28, 58/32, 58/36, 60/28, 60/32, 60/36, 62/28, 62/32, 62/36, 64/28, 64/32, 64/36, 66/28, 66/32, 66/36, 68/28, 68/32, 68/36, 70/28, 70/32, 70/36, 72/28, 72/32, 72/36, 74/28, 74/32, 74/36, 76/28, 76/32, 76/36
		JX 321	36/22, 38/22, 40/22, 42/22, 44/28, 46/28, 46/32, 48/28, 48/32, 50/28, 50/32, 52/28, 52/32, 52/36, 54/28, 54/32, 54/36, 56/28, 56/32, 56/36, 58/28, 58/32, 58/36, 60/28, 60/32, 60/36, 62/28, 62/32, 62/36, 64/28, 64/32, 64/36, 66/28, 66/32, 66/36, 68/28, 68/32, 68/36, 70/28, 70/32, 70/36, 72/28, 72/32, 72/36, 74/28, 74/32, 74/36, 76/28, 76/32, 76/36
		JX 322	36/22, 38/22, 40/22, 42/22, 44/28, 46/28, 46/32, 48/28, 48/32, 50/28, 50/32, 52/28, 52/32, 52/36, 54/28, 54/32, 54/36, 56/28, 56/32, 56/36, 58/28, 58/32, 58/36, 60/28, 60/32, 60/36, 62/28, 62/32, 62/36, 64/28, 64/32, 64/36, 66/28, 66/32, 66/36, 68/28, 68/32, 68/36, 70/28, 70/32, 70/36, 72/28, 72/32, 72/36, 74/28, 74/32, 74/36, 76/28, 76/32, 76/36
Ceramic ball head			
Product Name	GMDN Code	Product model	Product Size
Ceramic ball head	38156	JX 401	28S, 28M, 28L
		JX 402	32S, 32M, 32L, 32XL
		JX 403	36S, 36M, 36L, 36XL
Metal ball head			
Product Name	GMDN Code	Product model	Product Size
Metal ball head	33175	JX 4301	22S, 22M, 22L 28S, 28M, 28L, 28XL 32S, 32M, 32L, 32XL 36S, 36M, 36L, 36XL