

الآلية المعتمدة في تقييم الخيوط الجراحية :

- ١- ان تكون الشركة المنتجة للخيوط الجراحية مسجلة في وزارة الصحة .
- ٢- ان تمتلك شركات تصنيع المستلزمات الطبية الى شهادات الجودة المعتمدة عالميا (FDA أو GMP أو 13485 أو Iso او اي شهادة اخرى معتمدة عالميا)
- ٣- مراعاة منشأ الشركة ومنشأ الموقع التصنيعي .
- ٤- وجود اعمال سابقة للشركة (تعاقد سابق) مع الشركة العامة لتسويق الادوية والمستلزمات الطبية (كيماديا) ولا توجد اي مخالفات من ناحية النجاح بالتقييم السريري والمختبري والتجهيز .
- ٥- ان يتم تقييم الخيوط الجراحية اثناء الدراسة من قبل اللجنة الاستيرادية في الشركة العامة لتسويق الادوية والمستلزمات الطبية (كيماديا) من ناحية التقييم السريري .
- ٦- ان تكون متداولة في بلد المنشأ .
- ٧- ان تكون منتجات الشركة (الخيوط الجراحية) مسوقة في دول اخرى .

The mechanism adopted for evaluating surgical suture:

1. The manufacturer Com. Should be registered in MoH
2. The manufacturer companies of medical appliances should have quality certification that dependable in world (Iso or 13485 or GMP or FDA or any other dependable certification in world)
3. Taking into consideration origin of company and industrialized site
4. If there previously company works (previously conytaction) with Kimadia and there are no breaches in concerning the success in clinical laboratory and supplying evaluations
5. The surgical suture should evaluation within study period by import committee in Kimadia from clinical evaluation point
6. It should be current in origin country
7. The producers of company (surgical suture) should be marketed to another country .

الفقرة الخاصة بالنماذج

اولا :-

- وجوب قيام الشركات المجهزة بارسال نموذج عدد ٥٠ قطعة لغرض الفحص والتقييم وارسال نماذج لجميع مكونات السيت الواحد عدد ٥٠ قطعة لكل رمز وطني وبخلافه يهمل العطاء وعلى الشركات المقدمة لهذه المناقصة والتي قدمت نماذج ولم يتم ارساء المناقصة عليها سحب نماذجها خلال فترة شهر واحد من تاريخ ارساء المناقصة وبخلافه يحق لشركتنا التصرف بها .

- *The supplier companies have to send(50) samples for evaluation & testing purpose and send samples for full items per each set(50 samples for each National code) otherwise the offer will be neglected Companies that participate in this bid which submitted samples and not get the relegation have to draw their samples within one month from the date of relegation otherwise our company (Kimadia) has the right to deal with these samples .*

ثانياً :-

- يتم تزويد المركز الوطني للرقابة والبحوث الدوائية بنماذج عدد (٣ باكيت) لكل وجبة من الخيوط الجراحية لأغراض التحليل على ان يحتوي الباكيت الواحد على ١٢ خيط جراحي ويكون ذلك سياق عمل ثابت .

Second:

-The National Center For Drug Control & Research shall be provided with samples (3 pack) for each batch of surgical sutures for analysis purposes, provided that each pack contains (12) sutures & this shall be a fixed work context.

النماذج الخاصة بالسرنجات (سرنجات 0.05 ml)

- يتم تزويد المركز الوطني للرقابة والبحوث الدوائية بنماذج عدد (٥ باكيت x ١٠٠ سرنجة) لكل وجبة لأغراض التحليل ويكون ذلك سياق عمل ثابت.

Samples against syringe models (0.05 ml syringes):

- The National Center For Drug Control & Research shall be provided with samples (5 pack x 100 syringes) for each batch for analysis purposes & this shall be a fixed work context.

الشروط الخاصة بالمعينات السمعية

Notes:-

1. All must be programmed by suitable programming interface that compatible with company hearing aids. (F.O.C.)
2. Each hearing aids must be supplied with 12 batteries cell.
3. All accessories must be supplied like cables, flexes, shoes, and software, that suitable for hearing aids. (F.O.C.)
- 4- The number for the above notes from 1-3 must be specified by technical committee that inspect the tender in KIMADIA.
- 5- Hearing aid package (External (paper) + Internal (Plastic Hard)). (F.O.C.)
- 6- User Guide in Arabic Language with each Hearing Aids. (F.O.C.)

الشروط الخاصة بوقعة الاذن

DEVICE NAME: Auditory Function Screening Device (OAE)	3 Units
❖ Application: Allow hearing impairments to be detected quickly in the cochlear.	
❖ Heavy duty & compatible design.	
❖ Configuration: portable or hand held.	
❖ Screening method : DPOAE, TEOAE: <ul style="list-style-type: none"> • Right only: yes. • Left only: yes. 	
❖ Alarms (visual & audible): high artifact.	
❖ Printer.	
❖ Accessories. <ul style="list-style-type: none"> • Prope : Flexible + not lower than 80 cm. • Eartips. • Hand bag. 	
❖ Power supply: <ul style="list-style-type: none"> • Rechargeable battery : (lithium ion) or (6V) or (4AA). • Comes complete with heavy duty charger. 	
▪ <u>Environmental requirements</u> : the equipment suitable for work in the climate conditions in Iraq in terms of temperature & humidity.	
▪ Training the doctor who is in charge of audiology units and incorporating of the program of Auditory Function Screening Device (OAE) then he will train the medical staff in his institution تدريب الطبيب المسؤول في وحدات السمع والتخاطب والمشمول بالبرنامج الخاص باجهزة المسح السمعي والذي سيقوم بدوره بتدريب الملاكات الصحية في دائرته .	
▪ Registration & documentation programmes consist of:- <ol style="list-style-type: none"> 1- Supplying (2) Lap-Tops for every company has a relegating contract per every cochlear implant center. 2- Specifications of Lap-Top will be the propriety of technical committee. 3- Training will be on specialization Centers Committee. <p>- برامج التسجيل والتوثيق الالكتروني وتتكون من:-</p> <ol style="list-style-type: none"> ١- تجهيز كل شركة قوقعة محال عليها العقد لابتوب عدد (٢) لكل مركز زراعة قوقعة. ٢- مواصفات اللابتوب تكون من صلاحية اللجنة الفنية . ٣- التدريب يكون في هيئة المراكز التخصصية . 	

قائمة نماذج مواد الاطراف الصناعية

List Of General Material Models (A)

	National code	ITEM	unit
1	ALL-DE00-057	Pedlilen rigid foam	1kg
2	ALL-DE00-058	Hardener for pedilin rigid foam	1 kg
3	ALL-DE00-065	Pigment past caucasim(colour pastes for lamination resine,skin colour)	200 gm
4			
5	ALL-DE00-056	PVA lamination bags, dimentions in cm approx. (130x26x5)	4 pcs
6	ALL-DE00-051	PVA lamination bags, dimentions in cm approx. (100X26X5)	4pcs
7	ALL-DE00-060	Sealing resin	1 kg
8	ALL-DE00-061	lamination resin (80:20)	1kg
9	ALL-DE00-063	Hardening powder for lamination resin	30 gm
10	ALL-DE00-037	. Stump gel liner(polyurethan, copolymer, etc) with distal connection, thickness 6 mm, distal circumference diameter320mm.	2PC
11	ALL-DE20-073	transtibial suspension sealing sleeve made from gel , knee center Circumference size Large .	2PC
12	ALL-DE21-072	Gel stump socks, consist of two or three texture layers, with gel in between, length 38-49 cm.	2PC
13	ALL-RE21-474	Flexible lamination resin, weight (4-5) kg.	1kg

List Of Models For Lower Limb Prosthesis(L)

قائمة نماذج لمواد الاطراف الصناعية السفلى

	National code	ITEM	unit
1	ALL-RE00-497	S.A.C.H. Foot for men, heel height 10-20 mm, with toe, colour beige, Max. body weight 100-150 kg, thread M 8-10, size 26 cm	1 PC
2	ALL-RE00-534	Single axis foot for men, with toes, colour beige, heel height 10-20 mm, with double hols for the adapter, max.weight 75-150 Kg.Size 26 cm, left	1 PC
3	ALL-RE-509	Dynamic foot for men, heel height10-20mm, with toes, colour beige, max.body weight 100-150 Kg, thread M8-10, with dynamic properties, size 26cm,	1 PC
4	ALL-RE00-569	Carbon foot for syms stump, with lamination adapter, adjustment option (medio lateral, antero posterior, and rotation movements) between foot and adaptor, with its cover, with toes, colour beige size 26cm	1 PC
5	ALL-RE00-578	Carbon foot for symes stump with pyramid adaptor. With foot cover, with toes, colour beige size 26cm	1 PC
6	ALL-RE00-615	S.AC.H foot adaptor, Stainless Steel, M10 bolt	2 PC
7	ALL-RE00-619	Single axis foot adaptor, Stainless steel, with rubber bumpers, and two screws, for feet sizes26-30cm.	1 PC
8	ALL-RE00-630	Tube adaptor, Stainless Steel, with one side 4 adjustment screws, Ø 30 mm, length 400- 500 mm	2PC
9	ALL-RE00-636	Tube clamp adaptor, stainless steel, one side 4 adjustment screws, and one screw clamp in the other side, Ø 30 mm.	2 PC
10	ALL-RE00-671	Double sliding adapter, Titanium, above and below 4 adjustment screws, effective length approx. 75 mm	1PC
11	ALL-RE00-639	Tube clamp sliding adaptor with 4 adjustment screws above, and one screw clamp below, Titanium, Ø 30 mm	1PC
12	ALL-RE00641	Double adaptor,with 4 adjustment screws above and below, effective length 45 mm.	1PC
13	ALL-RE00-649	Socket adaptor, with 3-4 long laminations anchors, and pyramid , stainless steel, with lamination dummy	1PC
14	ALL-RE00-650	Rotatable socket adapter, with 3-4 long laminations anchors, and pyramid receiver (four adjustment screws), stainless steel, with lamination dummy.	1PC

15	ALL-RE00-659	Socket adaptor, with 3-4 long laminations anchors, and rotatable pyramid , stainless steel. With lamination dummy.	1PC
16	ALL-RE00-693	Polycentric knee joint with integrated extension assist, stainless steel. with pyramid above and below.	1PC
17	ALL-RE00-699	Polycentric knee joint, with hydraulic swing phase control. With pyramid above and below.	1PC
18	ALL-RE0-697	Monocentric knee joint with manual lock , pyramid above and distal connection tube clamp Ø 30 mm, stainless steel and/ or aluminium, with lock cable.	1PC
19	ALL-RE00-768	Shuttle lock with lamination anchor with pyramid below, and serrated pin, with its accessories	1PC
20	ALL-RE00-645	Rotation adaptor, Stainless steel or Titanium, with pyramid adaptor above and 4 adjustment screws below to allow leg rotation medially or laterally in relative to socket.	1PC
21	ALL-RE00-717	Hydraulic hip joint, for hip disarticulation	1PC
22	ALL-RE-669	Angled tube clamp adapter, Titanium or stainless steel Ø 30mm , pyramid receiver (4 adjustment screws) in one side and screw clamp in the other side, angled 10-20°.	1PC
23	ALL-RE00-722	Cosmetic foam cover, for transfemoral prosthesis, preshaped, calf circumference 44-46 cm, colour beige, length 90-100	1PC
24	ALL-RE00-721	Cosmetic foam cover, for transtibial levels, length 50-60 cm, for tube Ø 30-34 mm, preshaped, colour beige.	1PC
25	ALL-RE00-728	Cosmtic stocking, for transtibial prosthesis, perlon, length 40-46cm, colour beige	1PC
26	ALL-RE00-730	Cosmetic stocking, for transfemoral prosthesis, perlon, length 72-84 cm, colour beige.	1PC
27	ALL-RE00-742	Terry cloth stump sock for transtibial stump, length 45 - 60 cm	1PC
28	ALL-RE00-775	Flat rubber valve with thumb flap, with automatic air outlet, without valve ring.	3 PC
29	ALL-RE00-776	Seat ring for the above flat rubber valve, plastic.	2 PC
30	ALL-RE00-777	Connection tube with seat ring, plastic.	1PC
31	ALL-RE00-778	Screw valve kit, for thermoforming flexible socket.	1PC
32	ALL-RE00-416	Perlon stockinette for fabricating laminates, white,width 15 cm, weight 1 kg	1 roll
33	ALL-RE00-407	Woven carbon fiber glass stockinette for fabricating laminates, width 120mm, weight 1 kg.	1 roll

34	ALL-RE00-421	Nylglass stockinette for fabricating laminates, white,width 15 cm, weight 1 kg.	1 roll
35	ALL-RE00-430	Dacron Felt,for smooth inner surface after laminating socket , width 90 -100 cm, length 30 meter.	1 pc
36	ALL-RE00-457	Thermoforming foam sheet, for fabricating soft socket (pedilin), length 1 meter, width 1 meter, thickness 6 mm, flesh colour.	1 pc

List Of Tools

	National code	ITEM	unit
1	ALL-RE00-196	Surform replacement blad, half round, for fast shaping of plaster cast.	2 pc
2	ALL-RE18-197	surform holder(file), used as holder for the above surform	1 pc
3	ALL-RE00-198	Surform replcement blad, round, for fast shaping of plaster cast.	2 pc
4	ALL-RE18-199	surform holder(file), used as holder for the above surform	1 pc
5	ALL-RE18-200	Surform replcement blad, flat, for fast shaping of plaster cast.	2 pc
6	ALL-RE18-201	Surform holder(file), used as holder for the above surform.	1 pc
7	ALL-RE00-224	T-handled hexagon wrench, steel with plastic handle. Wrench size 4mm.	2 pc
8	ALL-RE00-225	T-handled hexagon wrench, steel with plastic handle. Wrench size 5 mm	2 pc
9	ALL-RE18-226	T- handled hexagon wrench, steel with plastic handle. Wrench size 8 mm.	2 pc
10	ALL-RE00-230	Teflon sheet, width 1300-1600 mm, thickness 0.22 mm. sevice part for oven.	1 pc
11	ALL-RE00-231	Plaster cast scissores, stainless steel , lower toothed blade	2 pc
12	ALL-RE00-247	Sanding drum, conical shape, with rubber body, length 60 mm, diameter 36/22. thread M 16 mm. service part for milling machine.	2 pc
13	ALL-RE00-205	Sanding sleeve used with the sanding drum above(T8), outside diameter 73mm, length 200 mm, grit 80	2 pc

14	ALL-RE00-204	Sanding sleeve used with the sanding drum above(T8), outside diameter 73mm, length 200 mm, grit 40.	2 pc
15	ALL-RE00-202	Rasp (grinding) head, service part for grinding machine, used for processing wood, foam. medium rasp stroke, thread M 16, diameter 50 mm, length approx(60- 100 mm), metal.	2 pc
16	ALL-RE18-258	Deburring knife, spare part for above tube cutter in item T201.	2 pc

Orthosis Materials List

قائمة بمواد المساند

	National code	ITEM	unit
1	ALL-RE18-337	Ankle joint with limited motion function, for bar width 16mm, left. [With its shoe stirrup size (18-20)cm].	1 pc
2	ALL-RE18-334	Ankle joint with dorsiflexion function, for bar width 20mm, left . [With its shoe stirrup size (18-20)cm].	1 pc
3	ALL-RE18-377	Knee joint for orthosis, contoured medial joint, straight lateral joint, with swiss lock, lock lever points upward, for side bar width 16mm, left, stainless steel.	1 pc
4	ALL-RE18-387	Knee joint for orthosis, contoured medial joint, straight lateral joint, with ring lock, for side bar width 20 mm, left, stainless steel.	1 pc
5	ALL-RE00-392	Polypropylene ankle foot orthosis, for foot drop. (L)	1 pc
6	ALL-RE18-393	Polypropylene ankle foot orthosis, for foot drop. (XL)	1 pc
7	ALL-RE00-291	Elbow joint for orthosis, stainless steel, with upper and lower bars and manual locking, flexion approx. 135°.	1 pc
8	ALL-RE00-310	Ring lock Knee joint with lateral bars for children, bar thickness 3 mm and width 12 mm. stainless steel or aluminium.	1 pc
9	ALL-RE00-365	Ring lock Knee joint with lateral bars for children, bar thickness 3 mm and width 16 mm. stainless steel or aluminium.	1 pc
10	ALL-RE00-368	Milwaukee spinal orthosis size M.	1 pc
11	ALL-RE00-373	Orthosis side bar set (upper and lower, right and left bars) for knee joint, width 16 mm, stainless steel, with adhesive.	1 pc
12	ALL-RE00-281	Orthosis side bar set (upper and lower, right and left bars) for knee joint, width 20 mm, stainless steel, with adhesive.	1 pc
13	ALL-RE00-438	Copper rivet, shank diameter 4mm, length 25-30 mm.	1 bag
14	ALL-RE00-454	Plastic for fabrication of orthosis without preparing a plaster cast or model, providing instant patient fitting, low	1 pc

		temperature (60-80 c), perforated,length 90 cm,width 60cm, thickness 3-4 mm, colour beige.(Turbocast,orthoplast).	
15	ALL-RE18-458	Thermoforming foam sheet, for orthosis padding (pedilin), length 1 meter, width 1 meter, thickness 3 mm. colour flesh colour.	1 pc
16	ALL-RE00-462	Plastazote nonperforated for orthosis padding, length 1 meter, width 1 meter, thickness 3 mm.	1 pc
17	ALL-RE21-407	"Pavlik-Harness used for treatment of congenital dislocation of the hip: Small-chest measurement 34 - 42 cm"	1 pc
18	ALL-RE21-410	Splint-Adjustable abduction hip frame for C.D.H used in congenital dislocation of the hip in children that require traction with gradual abduction	1 pc
19	ALL-RE18-472	Polypropylene copolymer sheet for orthosis, thickness 5mm, length 2 meter, width 1 meter, working temperature approx.(170-190 °c).	1 pc
20	ALL-RE00-285	Adjustable pin wrench tool (two hole nut driver), with hardened steel tips, adjustment using conical screw, with handle, used for round nut with two holes.	4pc
21	ALL-RE00-286	(Deburring) smoothing knife tool with replaceable blad, for smothing plastic and metals.	4pc
22	ALL-RE18-287	Replacement blade for deburring knife in item .	10 pc

Upper Limb Materials List (U)

قائمة بمواد الاطراف العليا

	National code	ITEM	UNIT
1	ALL-RE00-163	Myoelectric hand componants for above and below elbow amputation.function: opening and closing using 2 electrodes with supination and pronation. Size 7 3/4, left	1 pc
2	ALL-RE00-150	Modular componants for shoulder disarticulation(endoskeletal), with manual elbow lock, right.	1pc
3	ALL-RE00-153	Elbow and forearm Components(exoskeletal), with manual elbow lock, with different locking position(at least 5 position lock), forearm length approx. (250-280 mm), plastic, , beige color, with lamination ring above	1pc
4	ALL-RE00-005	Cosmetic gloves for men, metacarpal circumference 206mm, middle finger length 80 mm. Left , color 8.	1pc
5	ALL-RE00-006	Cosmetic gloves for men, metacarpal circumference 206mm, middle finger length 80 mm. Left , color 11.	1pc

6	ALL-RE00-054	Cosmetic Inner hand for men,metacarpal circumference 206mm, middle finger length 80 mm. Left , color beige.	2pc
7	ALL-RE00-148	Modular arm component for above elbow amputation(endoskeletal), with manual elbow lock, left.	1pc
8	ALL-RE00-147	Pre-shaped cosmetic foam cover for above elbow modular(endoskeletal) prostheses with its plastic connection ring,skin colour.	1pc
9	ALL-RE00-195	Myoelectric elbow joint	1pc
10	ALL-RE00-192	Moduler wrist unit(endoskeletal), to connect cosmetic inner hand with Modular arm component.	1pc
11	ALL-RE00-077	Cosmetic gloves for men with short sleeve .used for mechanical hand, Left , color 8.	1pc
12	ALL-RE00-079	Cosmetic gloves for men with short sleeve. Used for mechanical hand,right , color 8.	1pc
13	ALL-RE00-146	Below elbow suspension harness kit, for fixing the prosthetics socket and controlling body powered mechanical prostheses.	1pc
14	ALL-RE00-154	Elbow and forearm Components(exoskeletal), with cable mechanical elbow lock, with different locking position(at least 5 position lock), forearm length approx. (250-280 mm), plastic, , beige color, with lamination ring above.	1pc
15	ALL-RE00-182	Electronic tool, used to test muscle activity and train patient before using myoelectric hand.	1pc
16	ALL-RE00-183	Above elbow suspension harness kit, for fixing the prosthetics socket and controlling body powered mechanical prostheses.	1pc
17	ALL-RE18-190	Voluntary closing mechanical hand with cable,for men, right	1pc
18	ALL-RE00-159	Wood Hand adapter with stud , for connecting cosmetic inner hand with the forearm socket.	2 pc
19	ALL-RE00-193	Moduler wrist unit(endoskeletal), to connect mechanical inner hand with Modular arm component.	2 pc
20	ALL-RE00-181	Metal hand adapter(wrist unit) with rotation, for connecting mechanical inner hand with the forearm socket.	2 pc

Note:

A- Dependence the enclosed list against items that arrange by the committee for evaluation purpose to containment essential & fundamental items as per the technique committee opinion.

B- Upon sending the samples , it should has thermal printing or laser a company symbol or code item provided that compatible with symbols that state in as catalogue by the supplier company & it will neglect any sample not compatible with this terms.

C- Depend the samples that present with tender or evaluations against previous contracts in case there are evaluation for it & provided that there are no bad report for received contract in centers & the new offer that present should be compatible with samples that previous evaluated & in case present offer with new samples it should send that sample for evaluation purpose & training on it in case of need to training .

ملاحظة:

أ- اعتماد قائمة المواد المرفقة ربطا المعدة من قبل اللجنة لغرض التقييم لاحتوائها على المواد الاساسية والحيوية حسب راي اللجنة الفنية .

ب- عند ارسال النماذج يجب ان يحتوي النموذج على رمز الشركة او كود المادة طبع حراري او ليزري على ان يتطابق مع الرمز الموجود في

الكتلوكات المرسله الخاصة بالشركة المجهزة وسوف يهمل اي نموذج لا تنطبق عليه هذه الشروط.

ت- اعتماد النماذج المقدمة مع العطاء او التقييمات الخاصة بالعقود السابقة حال وجود تقييم لها وشرط عدم وجود تقارير سيئة لمواد العقود المستلمة في المراكز وعلى ان يكون العرض الجديد المقدم مطابق للنماذج المقيمة سابقا وفي حال تقديم عرض مع نموذج حديث يجب ارسال النموذج لغرض التقييم والتدريب عليه في حال الحاجة للتدريب .