TGA.

TABLED
Thursday
7 DEC.

Notes for Response to the Productivity Commission

Comparison of Cost - TGA and a European Notified Body for Quality Assurance System Certification under the Australia / EC - MRA.

Based on a published fees document provided to the TGA from a European Notified Body. A comparison of fees for an Annex II route to Conformity for Quality Assurance System Certification was performed in 1998. It was found that the European Notified bodies costs were approximately twice the amount of TGA's fees. This comparison excluded travel costs for the European Notified Body which would add more to the European costs. TGA fees for this type of certification have not significantly increased since 1998.

Costs were approximately $17,000 vs approximately $34,000
Notified Body was IMQ

To Peter Maclachlan

Keith Smith.

pIA – [illegible]

IMQ FEES	Section : Medical equipment	10
		1998

(1 UT = Lit 532.000)

10.1 *IMQ MARK, IMQ CERTIFICATE WITH SURVEILLANCE AND IMQ-UNI MARK*

10.1.1 **ENTRANCE FEE**
Not required.

10.1.2 **INSPECTION VISITS**
See 0.1.3.

10.1.3 **APPLICATION**
See 0.1.4.

10.1.4 **TYPE TESTS**
See column I of the table below and 0.1.5.
In case of verification to ascertain product conformity to Amdt. A2 of CEI 62-5:1991 Standard, where applicable, in addition to the amount stated in column I the following fees will be applied:
- electromagnetic compatibility tests : according to 80.2 of the Scale of fees;
- biocompatibility tests : at final balance, as per laboratory outside IMQ;
- assessment of safety requirement for programmable electronic controllers : 0.37 UT per hour

10.1.5 **LICENCE FEES**
Basic annual amount, as per item 0.1.6.
Variable annual amount, as per column II of the table below; of the two stated amounts the first one is applied up to the 10th model while the second one is applied from 11th model on.
For this purpose different models are considered all those having different type reference and/or different trade mark.

	PRODUCTS CATEGORY	COLUMN I Amount of one complete type test UT	COLUMN II Annual licence fees per model UT
1001	Medical equipment	at final balance	1.6-0.8
	- electrocardiographs	16.0	
	- electroencefalographs	17.0	
	- electromiographs	17.0	
	- cardiac-defibrillators	16.0	
	- defibrillator monitors	17.0	
	- high frequency electrosurgical equipment (< 50 W)	12.0	
	- high frequency electrosurgical equipment (> 50 W)	17.0	
	- patient monitors: (single channel)	14.5	
	(multi-channels)	18.5	
	- lung ventilators	16.0	
	- haemodialysis equipment	20.0	
	- baby incubators	18.5	
	- nerve and muscle stimulators	14.0	
	- scialytic lamps	9.0	
	- operating tables	14.5	
	- aerosol appliances	5.5	
	Additional charge for heater	1.0	
	- infusion pumps	14.0	
	- laser-therapy equipment	11.5	
	- laser-surgery equipment	18.0	0.4-0.25
	- modules for modular systems	at final balance	1.5-0.7
1002	Non-electrical medical devices	at final balance	1.6-0.8
1004	Whirlpool equipment for medical purposes	11.0	1.2-0.7
1007	Laboratory equipment	at final balance	
	- simple type (eg. mixer)	6.0	
	- average complexity type (eg. small analyzer)	13.0	
	- complex type (eg. multi-parameters analyzer)	20.0	1.6-0.8
1010	Appliances for dental purposes	at final balance	
	- dental chairs	13.5	
	- dental aspirators	10.5	

	PRODUCTS CATEGORY	COLUMN I Amount of one complete type test UT	COLUMN II Annual licence fees per model UT
1020	Appliances for radiology	at final balance	1.6-0.8
	- X-ray dental equipment	17.0	
	- mammography equipment	24.0	
	- movable equipment for ward and surgery room	24.0	
	- X-ray and radioscopy fixed systems	32.0	
1030	Hospital wall tubes		
	- with distribution system of liquids and medical gases	7.5	0.8-0.5
	- with lighting function only	7.5	
1050	Components and accessories for medical equipment	at final balance	0.5-0.3
	- antistatic wheels	at final balance	
	- accessories for electrosurgery	1.9	
	- accessories for lung ventilators and anaesthetic machines	1.3	
	- motors for medical equipment	2.6	
	- transformers for medical equipment	3.3	
1060	Beauty equipment	3.7	
		at final balance	1.5-0.7

10.1.6 ISSUING OF TEST REPORTS AND ATTESTATION OF CONFORMITY

• Application	0.2 UT	per model
• For carrying out tests and planning test report	0.28 UT	per hour of technician
• Test report	1.0 UT	per report
• Test report in case of complex equipment	2.0 UT	per report
• Test report in case of complex equipment tested according to several Standards	2.5 UT	per report
• Notification of Test Results (EMEDCA Agreement)	0.4 UT	per certificate
• Attestation of conformity	0.8 UT	

10.2 CE MARKING - ACTIVITY AS NOTIFIED BODY WITHIN 93/42/EEC DIRECTIVE

10.2.1 EC declaration of conformity (Annex II)

• Application for quality system approval	1.5 UT
• Application for design examination (Class III devices)	0.35 UT per products family
• Audit of the quality system	0.325 UT per hour travelling and out-of pocket expenses: at cost for IMQ + 10%
• Design examination (Class III devices)	0.325 UT per hour travelling and out-of pocket expenses: at cost for IMQ + 10%
• Declaration of approval of the quality system	0.4 UT per declaration
• EC design examination certificate (Class III devices)	0.4 UT per certificate
• Surveillance	

Basic annual amount (for approval declaration)
1.5 UT for firm who has a Quality System covered by a CSQ certificate
1.0 UT for firm who has a Quality System covered by a CSQ MED certificate
5.0 UT for firm who has not a Quality System covered by a CSQ certificate

Variable annual amount (for approval declaration)

2.0 UT up to 5 employees (0.5 UT if CSQ certified)
2.5 UT up to 15 employees (0.5 UT if CSQ certified)
5.0 UT up to 30 employees (1.0 UT if CSQ certified)
6.0 UT up to 60 employees (1.0 UT if CSQ certified)
7.0 UT up to 100 employees (1.0 UT if CSQ certified)
9.5 UT up to 250 employees (1.5 UT if CSQ certified)
13.0 UT over 250 employees (2.0 UT if CSQ certified)

10.2.2 **EC type-examination (Annex III)**

- Application for approval . . . . . 0.35 UT
- Verifications to ascertain that the essential requirements are fulfilled, including the preparation of the testing procedure . . . . . 0.28 UT per hour

Note. When the tests are carried out by other independent laboratories, they will be invoiced at final balance applying the rate of such laboratories.

- EC type-examination certificate . . . . . 0.8 UT per certificate

10.2.3 **EC verification (Annex IV)**

- Application for examination . . . . . 0.35 UT
- testing on samples or batches . . . . . 0.28 UT per hour

Note. When the tests are carried out by other independent laboratories, they will be invoiced at final balance applying the rate of such laboratories.

- Certificate of conformity related to performed tests . . . . . 0.8 UT per certificate

10.2.4 **EC declaration of conformity (Annex V)**

- Application for quality system approval . . . . . 1.5 UT
- Audit of the quality system . . . . . 0.325 UT per hour travelling and out- of pocket expenses: at cost for IMQ + 10%
- Declaration of approval of the quality system . . . . . 0.4 UT per declaration
- Surveillance

Basic annual amount (for approval declaration)

1.5 UT for firm who has a Quality System covered by a CSQ certificate
1.0 UT for firm who has a Quality System covered by a CSQ MED certificate
5.0 UT for firm who has not a Quality System covered by a CSQ certificate

Variable annual amount (for approval declaration)

1.0 UT up to 5 employees (0.5 UT if CSQ certified)
2.0 UT up to 15 employees (0.5 UT if CSQ certified)
4.0 UT up to 30 employees (1.0 UT if CSQ certified)
5.0 UT up to 60 employees (1.0 UT if CSQ certified)
6.0 UT up to 100 employees (1.0 UT if CSQ certified)
7.5 UT up to 250 employees (1.5 UT if CSQ certified)
11.0 UT over 250 employees (2.0 UT if CSQ certified)

10.2.5 **EC declaration of conformity (Annex VI)**

- Application for quality system approval . . . . . 1.5 UT
- Audit of the quality system . . . . . 0.325 UT per hour travelling and out- of pocket expenses: at cost for IMQ + 10%
- Declaration of approval of the quality system . . . . . 0.4 UT per declaration
- Surveillance

Basic annual amount (for approval declaration)

1.5 UT for firm who has a Quality System covered by a CSQ certificate
1.0 UT for firm who has a Quality System covered by a CSQ MED certificate
5.0 UT for firm who has not a Quality System covered by a CSQ certificate

Variable annual amount (for approval declaration)

1.0 UT	up to	5	employees	(0.5 UT	if CSQ certified)
1.5 UT	up to	15	employees	(0.5 UT	if CSQ certified)
3.0 UT	up to	30	employees	(1.0 UT	if CSQ certified)
4.0 UT	up to	60	employees	(1.0 UT	if CSQ certified)
4.5 UT	up to	100	employees	(1.5 UT	if CSQ certified)
6.0 UT	up to	250	employees	(2.0 UT	if CSQ certified)
9.0 UT	over	250	employees	(3.0 UT	if CSQ certified)

The fees stated under "Surveillance" cover all usual surveillance visits (assessment, travel and relevant expenses) carried out in Italy. For visits carried out in other Countries by IMQ, such amounts will be multiplied by the following coefficient:

- European Countries : 1.5
- Extra European Countries : 2.0

When surveillance visits are carried out by foreign Bodies, under the terms of specific agreements signed, the above fees will be proportionally reduced as per the achieved savings.

ELLEX
LASER SYSTEMS

2/7/99

18th June 1999

21 JUN 1999

Conformity Assessment Branch

Rita Maclachlan
TGA
PO Box 100
Woden ACT 2606

Taracan Pty. Ltd.
A.C.N. 008 276 060
trading as
ELLEX LASER SYSTEMS
258 Halifax Street, Adelaide
P.O. Box 7091, Hutt Street
S.A. 5000 Australia
Telephone 61-8-8223-6644
Facsimile 61-8-8232-6277
Email: ellex@enternet.com.au

Dear Rita,

It was a pleasure meeting you at last week's Trading with Europe Seminar. As requested, I enclose a copy of my presentation at that meeting, and trust it will be of some use to you.

You also asked if you could use my letter to Keith Smith dated May 3rd regarding the CE certification of our company, and I confirm that is OKAY.

Yours sincerely,

Keith R Degenhardt
Managing Director

RECEIVED
30 JUN 1999
National Manager
TGA

TGA

ELLEX
LASER SYSTEM

3rd May 1999

Taracan Pty. Ltd.
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ELLEX LASER SYSTEMS
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PO Box 7091 Hutt Street
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TGA
Mr K Smith
PO Box 100
Woden ACT 2606

Dear Mr Smith

I confirm receipt of the originals of the CE Certificates (Annex III and V of the Directive 93/42/EEC on Medical Devices), and the Quality System Certificate ISO9002/EN46002.

In accordance with the content of our accompanying letter dated April 28th 1999 I confirm acceptance of the removal of the reference to safety goggles from the contract for the performance of certification. I have noted your comments regarding the supply of safety goggles, and will proceed accordingly.

On behalf of everyone at Ellex involved in this project I wish to convey our thanks to you and the personnel at TGA who have acted in a timely and professional manner throughout.

Yours sincerely,

Keith R Degenhardt
Managing Director

FACSIMILE MESSAGE

— Registration

To: Ms Rita Maclachlan
Company: Acting Director CAB ,TGA
Country of Destination:
Facsimile No: (02) 6232 9687

From: Malcolm Plunkett
Position:
Date: 17/3/00

2 1 MAR 2000

Conformity Assessment Branch

Subject: CE-mark type testing
Pages including this one:

ELLEX
LASER SYSTEMS

Taracan Pty Ltd
A.C.N 008 276 060
trading as Ellex Laser Systems
258 Halifax Street
Adelaide S.A. 5000
Australia
Telephone No.: 61 8 8223 6644
Facsimile No.: 61 8 8232 6277
Email: mplunkett@laserexsystems.com.au

Dear Ms Maclachlan ,

I would like to take this opportunity to pass on our thanks to your department for the assistance provided by your staff in achieving CE-mark certification for a number of our models . The MRA has been a great success in our opinion and the experience we have gained over the last year from working with TGA has not only allowed us to sell our current products in Europe but is also allowing us to design the correct regulatory requirements into new designs .

In particular I would like to commend the work and assistance provided by Dragana Milic during the type testing of all of our models . Dragana has helped us to focus our attention on all factors that could affect patient or operator safety and the safety aspects of software design . I believe that the changes we have introduced after feedback from Dragana have definitely improved our safety design and our attitude to risk analysis . Having gone through several Annex 3 type tests with Dragana has also allowed us to develop a design and documentation approach which allows us to proceed with an ISO9001/46001 audit with some confidence .

Once again , thanks to all concerned .

Best regards ,

Malcolm Plunkett
Project Manager

Seal of approval

By Shelley Tang

The Therapeutic Goods Administration (TGA) has taken a bold step onto the world stage under new trade arrangements established with Europe.

From 1 January 1999 a Mutual Recognition Agreement (MRA) came into force between Australia and a number of major European countries, including France, Italy, Germany and the United Kingdom.

The MRA is a broad trade agreement that incorporates the medical device sector. Under this scheme designated agencies in Europe and Australia are recognised as capable of ensuring products meet the relevant standards before being allowed onto their respective markets. In Australia, the TGA has been given the role of assessing and approving products for sale in Europe.

At a recent seminar on Trading with Europe, organised by the Department of Industry, Science and Resources, Mr Keith Degenhardt, of Ellex Laser Systems, praised TGA for its professional and highly skilled approach to certifying products for the European market.

Mr Degenhardt described three years of unsuccessful attempts to certify a medical laser device using two private European certification bodies. When the MRA came into force, he contacted TGA, and reports that for the first time, found people who understood the requirements of the European system, and who shared the company's objective of getting the product approved.

Mr Degenhardt explained that TGA provided highly skilled technical people, including an expert in medical lasers. He found that its knowledge was greater than that of any of the European regulatory agencies with which his company had previously come into contact.

Ellex established a cooperative working relationship with the TGA, and received the appropriate certificates in April 1999.

It is TGA's goal that this will be just one of many successful outcomes in the new field of certifying Australian medical devices for the European market.

Shelley Tang works with the TGA's Device Registration and Assessment Section.

At leisure?

Six months into retirement and Rex Packer says he is adjusting well to his new 'career in enjoyment and relaxation'. Rex retired last December after 28 years with our Department and 45 years in the Australian Public Service.

Rex began work at age 14 as a telegram delivery boy for the Post Master General in Adelaide. His parents, survivors of the Great Depression and the Second World War, insisted on his having a secure job after he refused to return to school. In later years, Rex completed his studies at night, married and moved his family to Canberra to join our Department in 1971. In 1983 Rex transferred to Aged Care where he worked till last December. His days are now busy with church and community activities, travel and family. Rex's message to people considering retirement: 'Don't wait. Go for it!'

Rex Packer and wife Meryl, take a moment to plan their next trip into Australia's great outdoors. ***Photo: Norman Plant***

The occasional word

Pi jaw means...

a. a circular measurement

b. a keen pastry eater

c. a long dull moral lecture

d. a right angled hinge opening

Answer:

c. a long dull moral lecture

INTRODUCTION PARAGRAPH
KEITH DEGENHARDT - ELLEX LASER SYSTEMS

Keith Degenhardt is the Managing Director of Ellex Laser Systems. He has a 23 year background in marketing, the majority of it in the international medical market. He joined the original "Laserex" in 1987 as its Marketing Manager, then participated in a Management buy out of the assets of their medical division in 1990 and established Taracan Pty Ltd trading as Laserex Systems which became Ellex Laser Systems.

The company's core business is to develop and market medical laser products internationally. They have successfully developed and currently manufacture several ophthalmic laser systems based on Nd: YAG solid state laser technology.

Introduction

Our history begins in the mid eighties, with the establishment of Laserex as a publicly listed company in Adelaide, established to develop and manufacture lasers for medical use, principally ophthalmology, and in particular, a 'YAG' laser for use following cataract surgery.

In 1989 Laserex suffered a financial collapse like so many other high tech companies of the time and the medical laser business was subsequently the subject of a management buyout and Laserex Systems was born, eventually becoming Ellex Laser Systems in 1996 as we shrugged off the last vestiges of association with the pre-existing companies.

We employ about 80 people in design and development manufacturing and administration, at our facilities in the CBD of Adelaide, from which we export approximately 98% of our output.

We export to some 70 countries around the world through about 60 dealers, and have a sales subsidiary in Minneapolis Minnesota and do OEM manufacture for Alcon Surgical, the largest company worldwide in the ophthalmic field.

We are registered with the FDA, are routinely audited by them and all of our products are available for sale in the USA.

Our product range is specifically solid state laser surgical devices for use by ophthalmologists. Ophthalmology has been an innovative leader in the use of laser products in medicine, indeed the first medical lasers were used in ophthalmology in the 1960's.

We make several types (models) of Nd:YAG lasers for post cataract surgery use. We also make a green laser for work principally on the retina, to photocoagulate bleeding or proliferative blood vessels associated with various disease states of the eye. These products are all technically complex, but can be considered to be routine "tools of the trade" for a clinical ophthalmologist in most developed countries, and they all perform procedures that are well defined and widely performed.

Regulatory History

Europe

Even the old Laserex company did business with our medical lasers in Europe in the mid 80's. When we took over the company in 1989 we took over an established dealer network that has over the years grown and developed such that Europe is/has been a significant part of our business through that time (approximately 30%).

Interestingly though, we never entered the German market as even in the 80's they had a requirement for medical product registration with their department of health (Med GV) and that registration process required product type testing to (at that time) a raft of standards that were a mixture of IEC, DIN and in some cases drafts. We envisaged that it was too difficult, costly, and that as there was an existing medical laser business in Germany the cost/return outcome was not favourable; besides, we were doing good business in the rest of Europe.

In (I think) 1992, France launched a requirement for medical devices to be registered in that country - a process call Homologation. This was, I guess, our first brush with product registration in Europe. Homologation and the German registration requirement

was in essence, the precursor to CE marking in these countries. Our French dealer at the time, using a "grandfather" provision, and without consulting us commenced the Homologation process. Working with a local French consulting company he had our YAG laser "type tested", and presented us with a list of required changes. It was a small list and within our capabilities so we did it and provided an updated prototype which he resubmitted. A few months later we reviewed another list of non compliances, - this time twice as long as the first one. Not knowing any better, we worked through them, resubmitted and - guess what - yes, a new, even longer list. Thus ended our first attempt at the regulatory hurdles of Europe. Interestingly enough the only 2 countries in Europe with a significant laser/medical manufacturing industry were the only 2 countries with such regulatory requirements. It was however as a result of this exercise that we took a keen interest in the regulatory requirements movement of Europe as it moved towards the CE mark, and we started planning for its introduction and application to our products.

Then in 1995 came our first real exposure, working with Alcon Surgical in the USA to get the CE mark according to the MDD directive 93/42/EEC on the YAG laser we make for them.

This was prior to the mandated requirement for CE marking by July 1998, and we were one of the first lasers to be CE marked in accordance with this directive. To be fair, we mainly managed the technical side (type testing) with Alcon's assistance and they managed the process. Luckily they had affiliate companies in both France and Germany and their regulatory manager was an ex TUV Germany employee who understands the people and processes involved. With a relatively smooth path the

product achieved its CE mark in late 1995 and has been supplied in Europe through Alcon ever since.

During this time we were supplying our products CE marked to directive 89/336/EEC, basically tested and certified to the requirements for EMI/ESD, and we were working to have all our products CE marked in time for the mandatory requirement in mid 1998. A not unrealistic expectation given our past activity and success with the Alcon product - how wrong we were.

CE Marking - The Australian Experience

With a more than basic understanding of the process required we commenced travelling down the path that we thought would have us fully compliant in plenty of time. In the meantime we were still supplying Europe, with the exception of France and Germany, so disruption to our sales was minimal.

In late '95 we engaged the local services of a certification company that was a "notified body" in Europe, and proceeded to achieve certification to ISO9002. This required a restructure of our QA system which was FDA based.
It was our intention then to subject our products to type testing as had been done with the Alcon model and achieve the CE mark by an Annex III/Annex V approach. (It was always our intention to upgrade to ISO9001 when we had new product development that would have generated an audit trial for certification).

At this time however the information available at a detailed level about the process was very poor in Australia, especially from the certification providers.

As we dug into the requirements it became apparent when we asked questions of the local providers that there was very little understanding of the CE mark when it came to medical devices. For example, even though we had ISO9002, and drafts in place for ISO9001 our certifier could not upgrade us to the requirements of the EN46000 standards.

The local office was not qualified, and it turned out the head office in Sydney also had no one qualified. This in turn prompted discussion with their parent company in Europe where it was ascertained a suitably endorsed product specific auditor would need to be sent to Australia. This was OK but then we got into a debate about the route they would allow us to take - their view was we had to have EN46001 and undertake an Annex II path - something that was not appropriate either in time or design history, nor a requirement of the MDD - it was apparent that the providers were either not sufficiently familiar with the requirements of the MDD or were only structured one way - perhaps with their own interests at heart.

With ongoing delays, as the local office tried to get up to speed, postponed visits by their overseas "experts", and time slipping away we decided to switch horses and find a certification body that (a) knew what was required, and (b) could supply the services and people to get us through the process.

This time we engaged another Australian company, acting as an agent for one of the main European notified bodies. They appeared to understand our requirements, understand the process and even the local office advised they were able to supply the EN46000 certificate (indeed they already had for another Adelaide company). We had

our audit (QA system) duly received our ISO9002 certificate, and started asking where our EN certificate was - 6 months later we were still asking.
Back to square one. Of course the local office couldn't issue the EN certificate. The auditor was not qualified to audit medical systems, even though he claimed he could. They sent another person from Sydney. Another audit - but still no EN - his qualifications weren't recognised by the NB they acted for.
Eventually a representative of the NB was sent from overseas, another audit conducted and eventually an EN certificate provided - progress at last - but at considerable cost and delay, and a deteriorating relationship.

In parallel we undertook type testing of one of our products (the one most like the Alcon model we already had certified) EMI/ESD/IEC 601, IEC 825 etc etc.
Most testing was done by Australian NATA accredited test houses who were also part of the CB scheme.

We completed a technical file to satisfy the requirements of Annex III and then were told that the file and our product would have to be sent to a US test facility of the European N.B. for "evaluation".

This of course required significant time, and considerable cost and basically our technical file, and product were ripped to shreds - interesting as the same NB accepted the Alcon product - technically identical. What was worse, they rejected the findings of NATA accredited laboratories in Australia and advised that the attachment of a CB certificate were of no consequence, leaving us with no basis for discussion or resolution of issues that would have required an almost complete redesign of the product.

To be fair to the local representatives of this NB, they were as shocked as we were at the outcome, particularly the test house view of our Australian testing and 'went to bat' for us, all, unfortunately to no avail. Also the clock was running and we were now locked out of Europe, and decisions needed to be made quickly as we could not see a way forward on our current path.

T.G.A. and the M.R.A.

While the aforementioned disasters were taking place, we had been following the progress of the TGA and the MRA. We were sceptical of the time frames proposed, and of the ability of the TGA to provide the necessary service given our past experiences. In consulting with another Adelaide manufacturer, who had also sought the services of an International N.B. and had a similar experience, we found that TGA were in fact making significant progress, had appointed people with appropriate qualifications, and seemed to be ready for the point in time when they would get the go ahead.

Also, for the first time I found myself talking to people who clearly understood the process, understood in detail the path we had chosen and importantly, had the objective of assisting us to obtain the CE mark - something I had not felt was the objective of previous certifiers.

This is not to say however that the TGA set their levels any lower, but, that we were all working towards the same objective in a cooperative and harmonious way.

Once the MRA was firmly in place, and we had a good idea of when TGA would be able to release certification and issue its NB number (0805) we engaged their services, completed the paper work to enter a contractual arrangement and scheduled the appropriate audits.

These took place in February 1999. There was a Quality Systems audit to EN46002, and a concurrent audit by the "technical expert" of our product and technical file for the annex III certification, eventually leading to the annex 5 certificate and our ability to CE mark our first product.

The attached (1) time line shows our path to the CE mark.

The only consternation we suffered in the process was the longer than expected wait for the release of TGA's NB number after our audit (and payment of fees), but it eventually came through and future projects should be even smoother.

Our Step by Step Approach to Achieving the CE Mark

OK - That's the history - now the how.

At the onset it can be very confusing to try and implement the requirements of the MDD. Not that the requirements are all that unclear, but people's interpretations of them vary considerably. Its also a little difficult to determine exactly which of the MDD requirements go where when you undertake the path we did.

Attachment 2 is a summary of the steps we took leading to the successful outcome of the CE mark for one product.

Attachments 3 - 7 are examples of the type of procedures we have generated to ensure compliance with the conformity path we chose. (Note - examples only - not complete).

These essentially follow the standard paths outlined by all C.A.B.'s and are really checklists of things to be done.

I have prepared a series of questions that I believe an organisation needs to ask of itself before undertaking the process of marketing (particularly medical devices) in Europe.

Key Questions - Of Your Organisation

1. Do we, as an organisation want to be part of the European Market.
2. Do we understand the cost involved - not just the superficial costs of audits, but the real costs that may come from product and organisational changes required by the certification process.
3. Do we know enough to allow us to control the process instead of allowing the process, and the certification providers to control us.

If the answer is yes, then another series of questions needs to be asked of the certification provides to ensure you are going to make the right selection, that the costs are controlled and that the time frame is appropriate.

Certification Body Questions

1. Are they a notified body for the purposes of CE marking medical devices.

2. What is the level of service that can be provided ie local certification or certification by an overseas parent.

3. Can they provide "proof" of the audit qualifications of their auditors, particularly for specific medical devices.

4. Will they/can they provide a service for the conformity path you have chosen.

5. For product testing, what is acceptable/required:-
   (a) internal tests
   (b) approved laboratory tests
   (c) CB scheme reports

6. Can they provide a list of standards that they will apply to your product and organisation in the process - does it match your list.

7. What are the cost of:-
   Audits
   Travel
   Certification
   Maintenance

8. What is the audit frequency.

9. What is the experience of the product evaluation auditor in auditing your product - technical component.

I believe you need to go most of the way through the process I outlined earlier, before you are informed sufficiently to answer the former 3 questions, let alone get into meaningful discussions with a certification body.

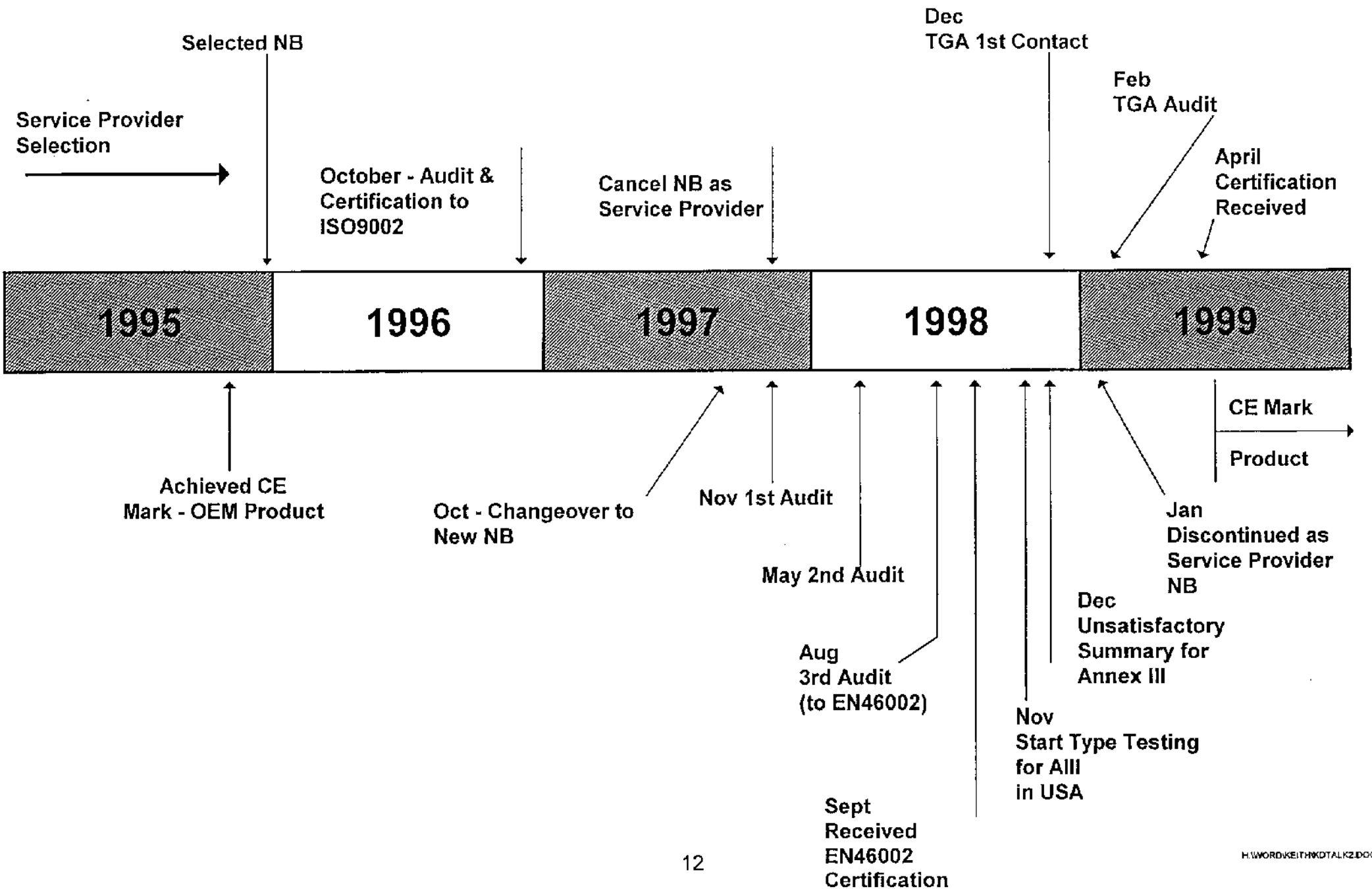
Once you receive satisfactory responses to these questions I believe you will be in good shape to make an informed decision about your certifier and should be in control of the process.

Of course, underlying this is the work it takes to get through all the vagaries of interpretation of the various standards, articles and directives by the various testers, evaluators, auditors etc, but perhaps that could be the content of another workshop.

Thank you

Attachment 1

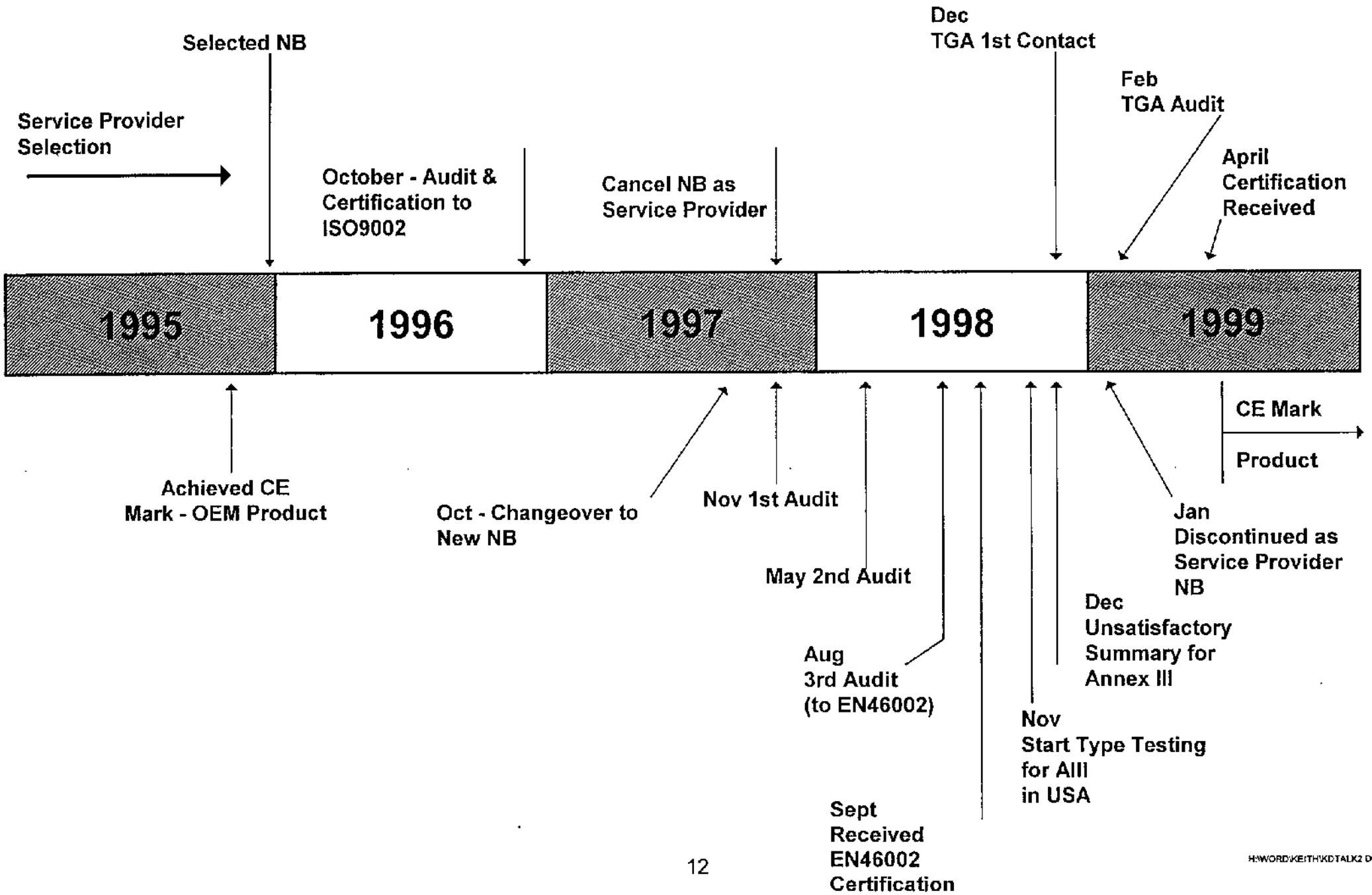
CE Mark Approval Process - Key Events - Time Line



H:\WORD\KEITH\KDTALK2.DOC

Attachment 1

CE Mark Approval Process - Key Events - Time Line



Objective: To meet the requirements of the applicable articles of the MDD.

Step 1. Identify applicable articles.

Essential Requirements (including standards)

Classification (of product)

Conformity assessment procedures

Step 3. Classify Product

Step 4. Choose conformity path

Annex III

Annex V

Step 5. Create Checklists for AIII and AV

Step 6. Show essential requirements have been met (AI).

Step 7. Audits to gain certification

Step 8. Complete declaration of conformity and affix CE mark

1. Scope

This procedure details the methods and documentation used to demonstrate product conformity to the Medical Devices Directive : Council Directive 93/42/EEC of 14th June 1993 concerning medical devices from the Council of the European Communities .
Successful product assessment by a notified body to the MDD requirements allows the CE-mark to applied , to allow sales within th EC .

2. Applicable documents

Medical Devices Directive : Council Directive 93/42/EEC of 14th June 1993

3. Procedure

Each article of the MDD should be reviewed to determine their relevence , however the main items that define the method of compliance are listed in the following table . This table can be used as a checklist and record sheet by recording the method to be used to demonstrate compliance . Examples are provided in each section but should be replaced with the actual method used .
The completed record sheet must be included in the conformity assessment section of the Technical File for the product .

Taracan Pty Ltd A.C.N. 008 276 060	Title : **MDD Conformity Assessment Procedure - Appendix 2** **Annex III - EC Type Examination Checklist** **(Showing method of compliance for each requirement of Annex III of MDD .)**	Code : PL-ECMDD.01 **Page:** 1 of 3

Annex III Requirements (summary)	*Documents in technical file*	*Code*	*Completed by*	*Comments*
2. Application to include :				
Name and address of manufacturer	Section A	(TF-3106.01)		
Documents described in section 3.	See below			
Declaration that no other application lodged for same product .	Section C Appendix 3 Declaration of conformity	(PL-3106R.01)	(Ellex / M.P.)	
3. Documentation required :				
General description & variants planned .	Section B Photodisruptor Device Family Description	(TD-PDIS.01)	(Ellex / M.P.)	
Design drawings , diagrams , circuits	Section G Module drawings and circuits			
Method of manufacture	Section G Manufacturing method			
Descriptions to explain drawings ,diagrams & operation	Section E Safety Characteristics Report Section H Operators Manual	(TS-PDIS.01)	(Ellex / M.P.) (Ellex)	
List of standards adopted to meet the essential requirements	Section C Appendix 3 Declaration of conformity	(PL-3106R.01)	(Ellex / M.P.)	

Author:	**Authorised By:**	**Date:**	**MODEL:**	**ASSESSED BY:** **CHECKEDBY:**	**DATE:** **DATE:**

Attachment 4

Taracan Pty Ltd A.C.N. 008 276 060	Title : MDD Conformity Assessment Procedure - Appendix 3 Annex V - EC Declaration of Conformity	Code : PL-ECMDD.01 Page: 1 of 3

MODEL: **ASSESSED BY:** **DATE:**
CHECKED BY: **DATE:**

1. Scope

This Appendix provides the documentation required to show compliance with Annex V of the Medical Devices Directive : Council Directive 93/42/EEC of 14th June 1993 .

2. Applicable documents

Medical Devices Directive : Council Directive 93/42/EEC of 14th June 1993

3. Quality System Certification

(A copy of the certificate which establishes that Ellex Laser Systems has in place a quality system which meets the requirements of ISO 9002 07.94 and EN46002 08.96 as required by Annex V of the MDD is attached .)

4. Declaration of conformance

(A declaration of conformance as required by Annex V of the MDD is attached .)

5. Example of CE Labeling

CE XXXX

Taracan Pty Ltd A.C.N. 008 276 060	Title : **MDD Conformity Assessment Procedure - Appendix 1** **Annex 1 - Essential Requirements Checklist** **(Showing method of compliance for each requirement of Annex I of MDD .)**	Code : PL-ECMDD.01 **Page:** 1 of 8

Annex I Essential Requirements (summary)	*Method used to fulfil requirement*		*Code*	*Completed by*	*Comments*
	Compliance to standard	*Documents in technical file*			
I . GENERAL REQUIREMENTS					
1. Device must not compromise the clinical condition or safety of patients or other persons . Risk associated with use must be acceptable in consideration of benefits to patient .		Software Validation Procedure Risk Assessment Safety characteristics report Complaint history report Clinical Data for Photodisruptors	(PL-Pdis3.01) (RA-PDis.01) (TS-PDis.01) (TH-PDis.01) (TC-PDis.01)	(Ellex / M.P.) (Ellex / M.P.) (Ellex / M.P.) (Ellex / M.P.) (Ellex / M.P.)	(to EN1441 guidelines)
2. Design and construction must conform to safety principals . Risks are to be reduced . Adequate protection measures . Information on risks provided	EN60601-1 EN60601-2-22 EN60825-1	Test Report Test Report EN60825-1 Verification Procedure	(76515) (76515B) PV-D825.01	(TCA) (TCA) Ellex /M.P.	
3. Device must perform as claimed .	EN60601-2-22 ENISO9002/EN46002	Test Report Certificate	(76515B)	(TCA)	
4. Device must not compromise the safety or performance during its lifetime .	EN60601-2-22	Test Report Complaint history report	(76515B) (TH-PDis.01)	(TCA) (Ellex / M.P.)	
5. Device must be unaffected by transport and storage .	EN60601-1	Test Report Complaint history report	(76515) (TH-PDis.01)	(TCA) (Ellex / M.P.)	
6. Undesirable side effects must be ~~persons~~ . acceptable in consideration of benefits to patient .		Risk Assessment Safety characteristics report Complaint history report Clinical Data for Photodisruptors Hazards list - Photodisruptors	(RA-PDis.01) (TS-PDis.01) (TH-PDis.01) (TC-PDis.01) (RH-PDis.01)	(Ellex / M.P.) (Ellex / M.P.) (Ellex / M.P.) (Ellex / M.P.) (Ellex / M.P.)	)(to EN1441 guidelines)

Author:	**Authorised By:**	**Date:**	**MODEL:**	**ASSESSED BY:** **CHECKED BY:**	**DATE:** **DATE:**

Attachment 6

Taracan Pty Ltd A.C.N. 008 276 060	Title : MDD Conformity Assessment Procedure - Appendix 3 Annex V - EC Declaration of Conformity	Code : PL-ECMDD.01 Page: 2 of 3

MODEL: **ASSESSED BY:** **DATE:**
CHECKED BY: **DATE:**

Declaration of Conformity

Manufacturer : Address :	Taracan Pty Ltd 258 Halifax Street Adelaide , South Australia , 5000
European Representative : Address :	Medtec Huttenberger Strabe 15 D-63776 Mombris , Germany
Product :	(Nd:YAG Ophthalmic Laser System)
Model :	(LQP3106)
Commencing serial number :	_____
Classification (MDD , Annex IX) :	(IIb)

We herewith declare that the above mentioned product conforms to the type described in the

EC type examination certificate _____ and

meets the provisions of the following EC Council Directives and Standards and that no other application for type-examination of the same product has been lodged with another notified body . All supporting documentations are retained under the premises of the manufacturer .

Directives and Standards

General applicable directives

Medical Devices Directive : Council Directive 93/42/EEC of 14th June 1993 concerning medical devices .

Standards

EN60601-1 (1998)
EN601-2-22 (1996)
EN55011 (1991)
EN50082-1 (1992)

Notified Body _____
_____

Signature : _____ Date: _____

Name : Keith Degenhart
Position : Managing Director