

1.

Dental technician qualification
Custom-made devices

What is a Dental technician and what a technician can do:

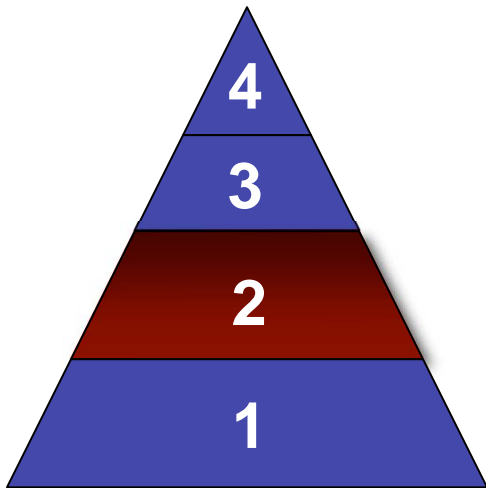
- Manufacturer of custom made devices
- You have to be registered with the SADTC
- These devices are manufactures in a dental laboratory / manufacturing facility.

Explanation of what a custom made device is:

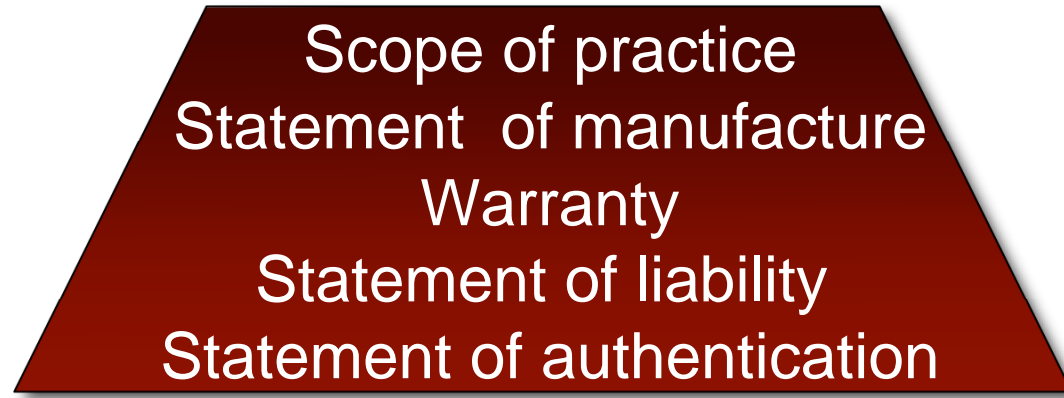
- A item that is custom designed, custom manufactured and custom fitted - a combination of all 3 makes it a custom-made device.
- There are different categories of custom made devices

According to the Act.:

- A Custom made device can only be manufactured for a specific patient.



2.



Scope of Profession

Dental technicians/technologists manufacture custom made devices concerning the head and its cavities, mainly the oral cavity. These appliances are manufactured in registered dental laboratories/ manufacturing facilities, by registered dental technicians/technologists on prescription from a dental clinician or other relevant medical clinician. Appliances/devices vary a great deal and may include fixed and removable orthodontic devices, non-metallic and metallic partial or full dentures; crowns, bridges and maxillo-facial prosthesis either tissue born, tooth born or implant supported as well as anti snoring, sleep apnea and headache or similar custom made devices. Dental technicians/technologists do not deal with the patient directly. After the completion of the dental/medical or custom made device, and final inspection by the dental technician or technologist, it is send to the relevant dental/medical clinician who then custom fits the device.

In South Africa there is a difference between the qualification of a dental technician and a dental technologist. The scope of practice for both are much the same, with some exceptions as indicated below.

A **dental technician** is formally trained at a recognized institution to a NQF level 6 qualifications in dental technology, and is registered with the South African Dental Technicians Council.

Qualifications for a dental technician will include:

- National Diploma in Dental Technology from a recognized South African institution.
- An approved overseas dental technology qualification, together with the successful (50% a pass) completion of a registration examination as prescribed by the SADTC.

A **dental technologist** is formally trained at a recognized institution to a NQF level 7 qualifications in dental technology, and is registered with the South African Dental Technicians Council. Qualifications for a dental technologist:

- B-Tech degree in Dental Technology from a recognized South African institution.

For the purpose of the Scope of Profession the following qualifications will be considered the equivalent of a dental technologist:

- A registration with SADTC after the successfully completion of registered apprenticeship plus 3 years appropriate post registration work experience.
- Diploma: Dental Technology (SADTC) plus 3 years appropriate post registration work experience.
- Higher Diploma in Dental Technology from a recognized South African institution plus 3 years appropriate post registration work experience.
- An approved overseas dental technology qualification, together with the successful (50% a pass) completion of a registration examination as prescribed by the SADTC.

Scope of Practice for Dental Technicians defined:

Qualified and registered dental technicians and dental technologists are the only persons who may do the work as described in the scope of practice as stipulated below. A dental technician may be employed to do the following work in a registered dental laboratory/ manufacturing facility, under the direct supervision of a dental technician contractor/dental technologist, a relevant dental clinician or appropriate clinical professional:

- carry out infection control procedures to prevent physical, chemical and microbiological contamination in the laboratory/ manufacturing facility.
- select appropriate materials for the design, manufacture and repair of fixed and removable custom made device as prescribed by a relevant practicing dental clinician or other appropriate clinical professional.
- design, plan and manufacture a range of custom-made fixed or removable custom made device according to a written prescription or verbal instruction by a relevant practicing dental clinician or other appropriate clinical professional.
- repair and modify fixed or removable custom made device on the instruction of a relevant dental clinician or other appropriate clinical professional.
- carry out shade taking if requested by a relevant practicing dental/medical clinician.
- verify and take responsibility for the quality and safety of devices leaving the dental laboratory in as far as appropriate to the profession.
- supervise a dental laboratory assistant.

Dental technicians may not:

- be a dental technician contractor or supervise a registered dental laboratory/ manufacturing facility
- perform clinical procedures or fit custom made devices
- provide treatment for or give clinical advice to patients

Practice in this context goes wider than dental technology. It includes teaching, research and management, given that such does influence clinical and technical practice and public safety. Areas of dental technology practice which were not included in a practitioner's training should not be undertaken unless the practitioner has successfully completed appropriate training and practices to the standard required by the relevant Scope of Practice.

Scope of Practice for Dental Technologists defined:

The Scope of Practice for dental technologists is essentially the same as that of dental technicians as defined in this document under the 'Scope of Practice for Dental Technicians' with the following exception:

Dental technologist may:

- be a dental technician contractor, and/or supervise a dental laboratory.
- employ dental technicians, laboratory assistants.
- review cases coming into the laboratory to decide how they should progress.
- work with the a relevant dental clinician or appropriate clinical professional on treatment planning and design of a custom made device appliance for a specific patient.

Dental technologists may not:

- perform clinical procedures
- Custom fit custom made device without the written consent of a relevant practicing dental/medical clinician
- provide treatment for or give clinical advice to patients

Practice in this context goes wider than dental technology. It includes teaching, research and management, given that such does influence clinical and technical practice and public safety. Areas of dental technology practice which were not included in a practitioner's training should not be undertaken unless the practitioner has successfully completed appropriate training and practices to the standard required by the relevant Scope of Practice.

Statement of Manufacturing

SUMMARY OF THE GUIDANCE NOTES REGARDING THE ACTIVITIES TO BE UNDERTAKEN BY DENTAL LABORATORIES / MANUFACTURING FACILITIES TO MEET THE REQUIREMENTS OF THE MEDICAL DEVICES DIRECTIVE

STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES

The manufacturer of a custom-made device must draw up a statement for each device which contains the information shown.

MANUFACTURING UNDER CONTROLLED CONDITIONS

The manufacturer must be able to demonstrate that work is being carried out under controlled conditions. This will include:

- *A documented review of the relevant clinical professional requirements (to demonstrate an understanding of the manufacturing requirements for the design). The processing parameters must be defined together with the choice of materials used. CE marked materials should be used.*
- *Defined manufacturing processes (eg work instructions).*
- *Suitably qualified personnel.*
- *Where appropriate, calibration and maintenance of equipment (eg thickness gauges).*
- *Cleanliness and cross-infection controls.*
- *Defined handling activities and packaging requirements.*
- *A documented review of the final product, against the relevant clinical professional initial requirements before it is supplied. Records should be maintained for a period of time of at least 5 years to demonstrate manufacturing control. These will include: the statement as defined in (1.) above, the review of the relevant clinical professional requirements and final product, identification of the materials used, production process monitoring and maintenance and calibration.*

THE MINIMUM REQUIREMENTS REGARDING THE LABELLING OF A CUSTOM-MADE DEVICES SHOULD INCLUDE:

- *The name or trade name and address of the manufacturer(s).*
- *The details strictly necessary for the user to identify the device and the contents of the packaging.*
- *The words custom-made.*
- *Any special storage and/or handling conditions.*
- *Any warnings and/or precaution's to take.*

However it is for the manufacturer of the device to review all the information and labeling requirements against his practices and authenticate it.

Data that should appear on invoice

For every device there must be a statement which contains the following information:

- *data allowing identification of the device in question,*
- *a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient,*
- *the name of the clinical profession or other authorised person who made out the prescription and, where applicable, the name of the clinic concerned,*
- *the particular features of the device as specified in the relevant prescription,*
- *a statement that the device in question conforms to the essential requirements and where applicable, indicating which essential requirements have not been fully met, together with the reasons of non-compliance.*

Statement of liability

Right to demand quality service

•Consumers are entitled to the following, when entering into agreements/contracts with the custom made device manufacturer

Timely performance and completion of those services;

Timely notice of any unavoidable delays in the performance of the services;

High-quality services they are entitled and expected; and

Supply of custom made devices that are free of defects and of a quality that persons are generally entitled to expect.

•Manufacturers are required to remedy any defects in the quality of manufactured custom made devices supplied; or refund the consumers a reasonable **portion of the price paid** (only after all other avenues were exhausted to remedy the situation, including independent arbitrator) for device supplied, in the event of these being sub-standard.

Right to safe, good quality custom made devices

Consumers are entitled to receive devices that are of good quality, in good working order and free of any defects, and that comply with any applicable standards set by the Regulator.

Right to implied warranty of quality

It is an implied provision that the producer or importer, distributor and retailer each warrant that the device comply with the requirements and standards of being safe, of good quality and durable to the extent of its expected lifetime.

Consumers are permitted to return device to the custom made device manufacturer, without penalty and at the custom made device manufacturer risk and expense, within a period of **21 days after delivery** of such devices, if the devices are of inferior quality, unsafe or defective.

Right to receive warnings on the fact and nature of risks

The manufacturer obliged to make consumer aware of any risks of an unusual character or nature, as well as risks of which consumers could not reasonably be expected to be aware, or which could not reasonably be expected to contemplate, depending on the specific circumstances or risk that could result in serious injury or death.

Custom made device manufacturer are obliged to bring to the Consumers' attention notice/labelling of any hazardous or unsafe device, and provide the Consumers with adequate instructions for the safe handling and use of those devices.

Devices that by their nature, because of their limited lifespan cannot be covered for 6 months:

Due to the fact that the materials used in the device may not be known and that there may be other factors involved like e.g. the device is past its life expectancy, or that patient use of the device may be contraindicated to norms.

Devices with a time limited usage and thus designed to be used for a limited time.

- Orthodontic devices
- Bite plates
- Temporary crowns
- Gum/Mouth guards
- Bleaching trays
- Ect.

Right to claim damages for excepted liabilities by the manufacturer

- For any harm caused wholly or in part, as a consequence of the following:
- Supplying any unsafe devices;
- Product failure, defect or hazard in any devices; or
- Inadequate information or warnings provided to the consumer pertaining to any hazard arising from the device of which the harm resulted from negligence on the part of the manufacturer.

Claiming procedure for devices under warranty.

If any device is to be unsafe, harmful or not to conform to manufacturing standards.

Manufacturer will have 6 months to correct the situation.

If the problem is not resolved within a period of 6 months the consumer has the right to independent arbitration.

All warranted devices will be partly warranted for 36 months

- 0-6 months no charge
- 6-18 months a reduced fee of 70%
- 18-30 months a reduced fee of 50%
- 30-36 months a reduced fee of 25%

NB! Warranties are null and void:

Where consumers are found to be misusing or abusing devices, while under warranty.

Where the prescribing clinical professional instructed the laboratory/ manufacturing facility to proceed against the recommendation of the dental laboratory / manufacturing facility and the onus will be with the prescribing clinical professional

All prescription are considered to be contracts.

Due to the nature of the custom made devices, there is no intrinsic value attached to the device, except to the person who it is manufactured for, thus:

A deposit is payable with the prescription and the balance on completion.

The manufacturer reserves the right to except a medical aid authorisation number.

Warranty for work done in a dental laboratory/manufacturing facility.

Devices/materials

Work produced in a dental laboratory/ manufacturing facility is guaranteed to be free of defects due to any of the materials used in the manufacturing/repairing of custom made devices.

Workmanship

Workmanship and the devices is guaranteed to fit the model/s and to be constructed in accordance with the design requested and specified by the clinical professional on the prescription form.

The warranty will be valid from the date of delivery

Exclusions

The following shall not be covered by dental laboratory/ manufacturing facility warranty:

- cash refunds for any custom-made devices;
- costs incurred for the removal or custom fit of any custom made device or and component thereof;
- repairs resulting from accidental damage of any kind by either the consumer or prescribed clinical professional;
- negligence on the side of the consumer or prescribed clinical professional;
- any form of abuse by the consumer of the device including using such device for purposes not normally intended;
- Failure of clinical supportive structures;
- any adjustments made or attempted by the consumer,
- any unreasonable adjustment/s attempted by the prescribed clinical professional;
- inadequate dental hygiene on the side of the consumer or poor instructions to the consumer from the prescribed clinical professional;
- any alteration/s or restorations partially or completely fabricated by any dental lablaboratory/ manufacturing facility other than the one who originally produced such device.

How the Warranty Works

If during the applicable warranty/liability period the consumer experiences any problems with a device that are covered by the warranty as described herein, the consumer may elect any of the following:

- Remake/Repair during the warranty/liability period. The manufacturer will remake or repair the device or part thereof, provided that if the consumer elects to change the material/s used in the fabrication for such device or part thereof, the original cost of the device or part thereof will be credited and the new costs invoiced.
- No cash refunds will be issued.

Conditions

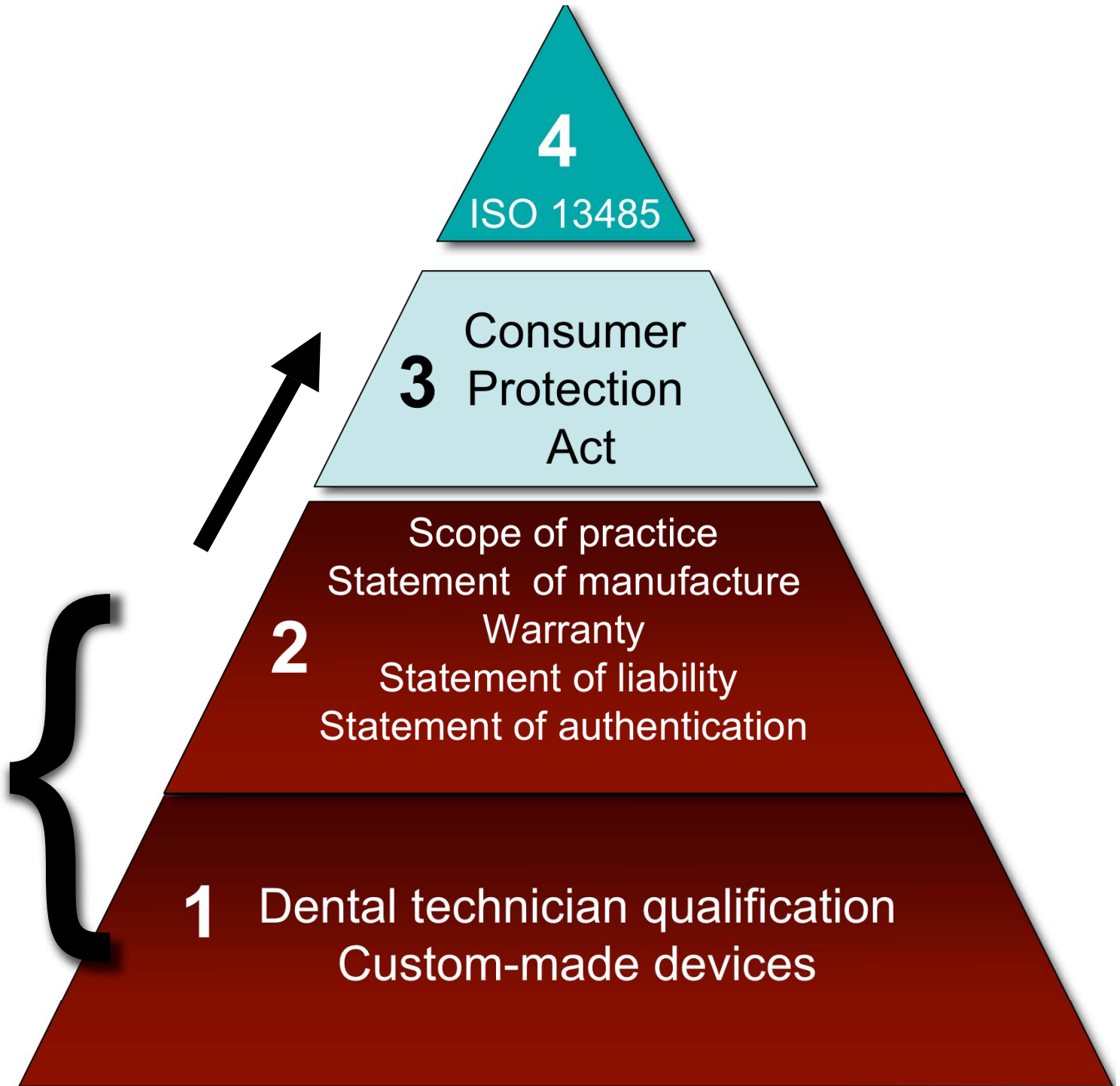
In order for the consumer to receive the benefits of the warranty/liability, the consumer agrees as follows:

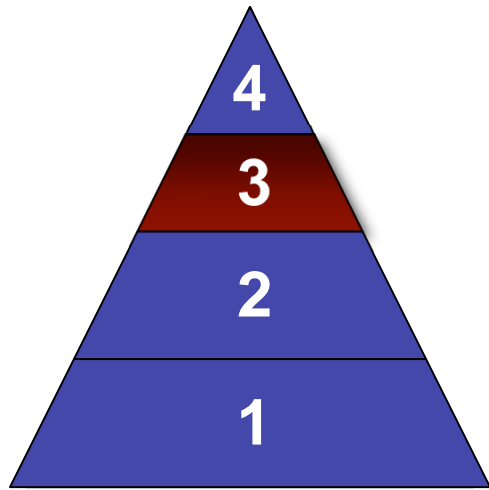
- The customer must provide the manufacturer with proof-of-purchase, including the original invoice together with the consumers name and statement/certificate of authenticity;
- The original custom made device or part thereof, including any damaged, severed or detached pieces, must be returned in order to allow the manufacturer to maintain its quality certification;
- The restoration must be inserted by a relevant clinical professional; and
- If the manufacturer requests a new impression, but is instructed by the customer to proceed without such new impression, the warranty/guarantee/liability cover shall be null and void and any further manufacturing, alterations or working upon will be completed at full cost to the consumer.

Conditions which MUST be met for the Warranty/liability to apply:

- All custom made devices or part thereof must be custom fitted by a relevant clinical professional.
- Consumers must adhere to a six monthly clinical maintenance programme in the office of a relevant clinical professional and which must include a full examination and hygiene in inspection.
- The maintenance schedule on the Certificate of authenticity must be documented by the attending relevant clinical professional after each visit to validate this warranty/liability.
- Any warranty becomes void if the customer does not adhere to a six monthly clinical maintenance programme and hygiene consultation, as is in the case of damage or destruction due to trauma or restoration failure due to oral facial and other related health problems.

Step 1 and 2 is what is needed to comply with the CPA





3.



The Purpose of the act is:

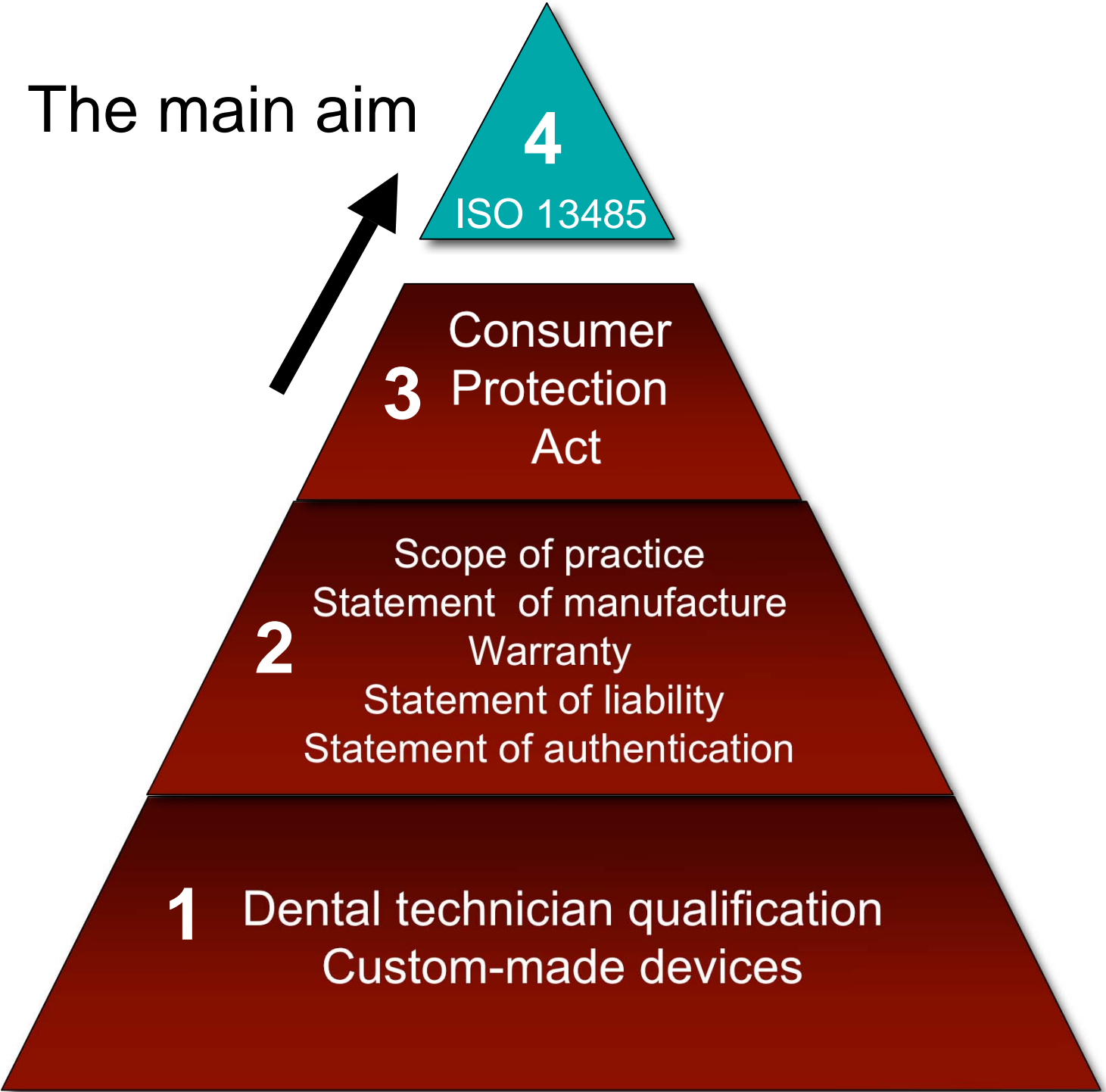
- Protecting consumers from unfair, unjust, and unconscionable business practice;
- Providing accessible and efficient dispute resolution and redress for consumer;
- Establishing a legal framework for a market is fair, accessible, efficient, sustainable and responsible;
- Reducing disadvantages to consumers who are-
 - In low income groups;
 - Who live in remote and isolated areas;
 - Who are minors, seniors or similarly vulnerable;
 - Whose ability to react and comprehend advertisements, agreements, labels and instructions are limited;
- Promoting fair business practices;
- Improving consumer awareness;
- Enhance consumer safety.

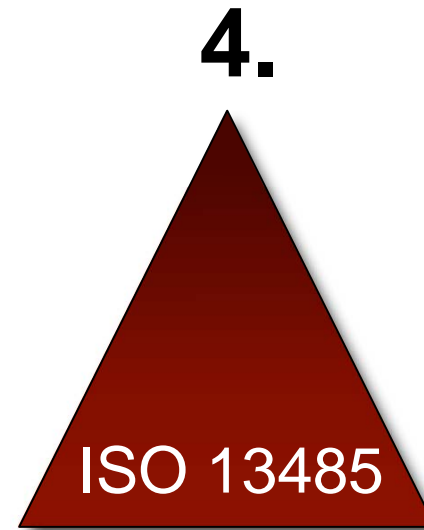
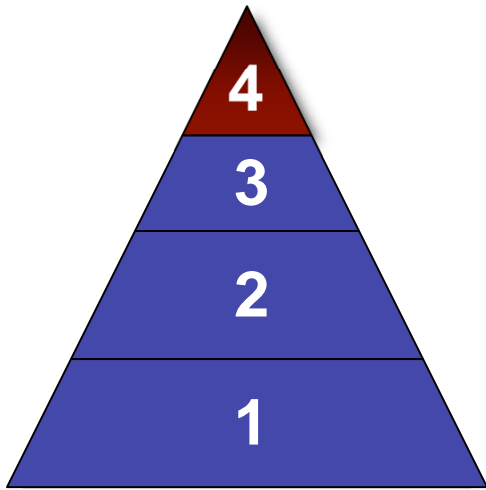
The Act therefore regulates:

- Marketing of goods and services;
- Warranties and guarantees;
- Cooling off periods;
- Lay by's;
- Forfeiture of goods by suppliers;
- Record keeping;
- Delivery of goods and services;
- Discrimination against consumers;
- Consumer's privacy;
- Language to be used in documentation;
- Franchise agreements to a certain extent;
- Dispute resolution and consumer commission powers;
- Fines and penalties to suppliers.

Suppliers beware of:

- Forfeiture of unsolicited goods without receiving payment;
- Search and seizure powers by inspectors;
- Fines of up to 10% of turnover or R1 million;
- Damages payable to consumer even where the supplier is not acting negligently or intentional;
- Minimum warranties & guarantees in terms of legislation;
- Illegal marketing methods;
- Fixed term agreements with consumers.





Definition: ISO 13485 is an ISO standard, published in 2003, that represents the requirements for a comprehensive management system for the design and manufacture of medical devices

The main aim

Without the ISO 13485:

You will not be able to export work from South Africa, from 2012.

South African dentists and laboratories will be able to outsource work to China, India ect.

With ISO 13485:

You will be able to market yourself globally.

You will be able to export to any country in the world.

As of 2012 ISO 13485 will be the world standard

