



Welcome all
dental technicians
to the

DENTASA
Road Trip 2011



CONSUMER PROTECTION ACT



**I KNOW MY
RIGHTS.
DO YOU KNOW
YOURS?**

You have rights as a consumer.
Understand them.
Enforce them.

Statement of Liability

Right to demand quality service

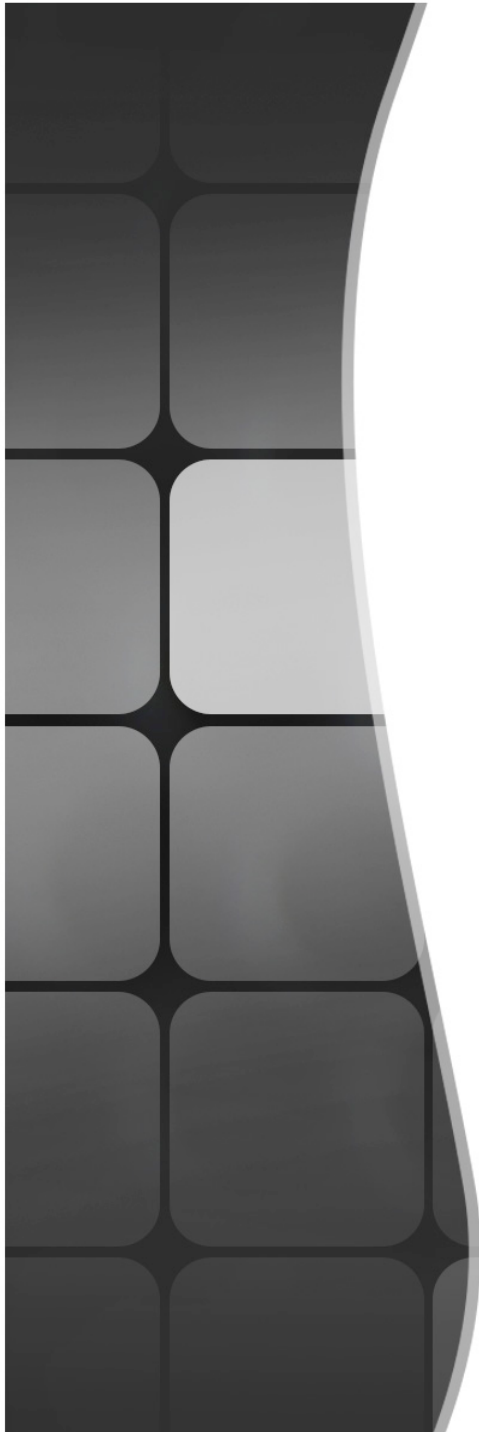
- Consumers are entitled to the following, when a prescribing clinical professional enters into agreements/contracts with the custom made device manufacturer
- Timely performance and completion of those services;
- Timely notice of any unavoidable delays in the performance of the services;
- High-quality services they are entitled to and expect; and
- Supply of custom made devices that are free of defects and of a quality that consumers are generally entitled to expect.
- Manufacturers are required to remedy any defects in the quality of the 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 arbitration) 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's 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

- Custom made device manufacturers are obliged to bring to the prescribing clinical professional's attention notice/labelling of any hazardous or unsafe device, in order for the prescribing clinical professional to provide the consumer with adequate instructions for the safe handling and use of those devices.
- The prescribing clinical professional is 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.

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

- Due to the fact that the materials used in the device may not be known materials incompatibilities may occur with repairs.
- 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 contraindicative to norms.
- Implant supported frameworks, veneering materials, dento-alveolar prostheses and dentures on meso- and/or solder bars. This is due to possible reduced neurological feedback and/or unpredictable parafunction and occlusal forces.
- Repairs covered for 3 months.

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
- Etc.
- These devices will be covered for their expected service time.



Right to claim damages for accepted 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 caused by non-compliance of product specific approved standards as set down by The Medicines and Medical Devices Regulator; 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, the 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 would 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 manufacturer to proceed against the recommendation of the manufacturer, the liability will transfer to the prescribing clinical professional

All prescriptions 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 authorization number.



1.

Prescription from Clinical Professional

- Dentists are clinical professional people.
- The prescription must be read carefully and be fully understood.
- There can no longer be guess work or experimenting.
- The prescription must always be signed by the dentist.

2.

Impressions

- This is the start of the Certificate of Manufacture.
- Impressions must be checked before the models are cast.
- If there is anything wrong with the models preventing you from making the device properly, the dentist must be informed immediately.
- Any faults must be documented.

3.

Models

- Once the models have been cast you must do an internal quality control check.
- The type of material used and quality of the model must be recorded on the Certificate of Manufacture.

3.

Models

- If there are any problems preventing you from designing the device to the dentists specifications, the dentist must be notified.
- If he insists to continue the certificate must be marked: Onus is on the dentist. The reason must be specified.
Responsibility is on the dentist.
- If the device is at the “final stage” (Models, bite block etc.) an internal quality control check is needed. If it is not at the “final stage” the model can go to a different department in the lab and no internal quality control check is needed.

4.

Manufacturing of device

- After waxing of a denture or casting of copings the next internal QCC is needed.
- It is important that the person manufacturing the device is not the person doing the internal QCC.(If you are a one man laboratory this will be unavoidable.)
- Final QCC must be done by dentist.

4.

Manufacturing of device

- This sequence will continue until the device has its final internal QCC before shipping to the dentist.
- The registered supervisor of the manufacturing facility must sign off on the completed custom made device.(Internal QCC.)

REMEMBER: At every stage where a furnace is used, record the temperature, and record material lot numbers and batch numbers.

5.

Shipping

- Once your final internal QCC has been completed you must check that all controls has been signed on the Certificate of Manufacture.
- Complete the statement and delivery note. (Most computers, with the right programs, can do both for you at the same time).
- With the statement and delivery note a Certificate of Warranty must also accompany the device, with work details and provision for the clinical professional to sign. The patient must adhere to the 6 monthly cyclic checkup for the warranty to stay valid.

5.

Shipping

- The device must be placed on its own in a plastic bag that is inserted into another bag with the relevant documents.(Statement, Delivery note, Certificate of warranty.)
- A sticker must be placed on the bag:



- Your case is now ready to be delivered.
- The delivery note must be signed by the dentist and sent back.



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

Devices/materials

Materials used in the manufacturing/repairing of the custom made device/s shall conform to regulations as set out by The Medicines and Medical Devices Regulator, and are guaranteed to be free of defects.

Manufacturing standards

The devices are 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 manufacturer's warranty:

- cash refunds for any custom-made devices;
- costs incurred for the removal or custom fitting of any custom made device or and component thereof;
- repairs resulting from accidental damage of any kind by either the consumer or prescribing clinical professional;
- negligence on the side of the consumer or prescribing 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 prescribing clinical professional;
- inadequate dental hygiene on the side of the consumer or poor instructions to the consumer from the prescribing clinical professional;
- any alteration/s or restorations partially or completely fabricated by any manufacturer other than the one who originally produced such device.



How the Warranty Works

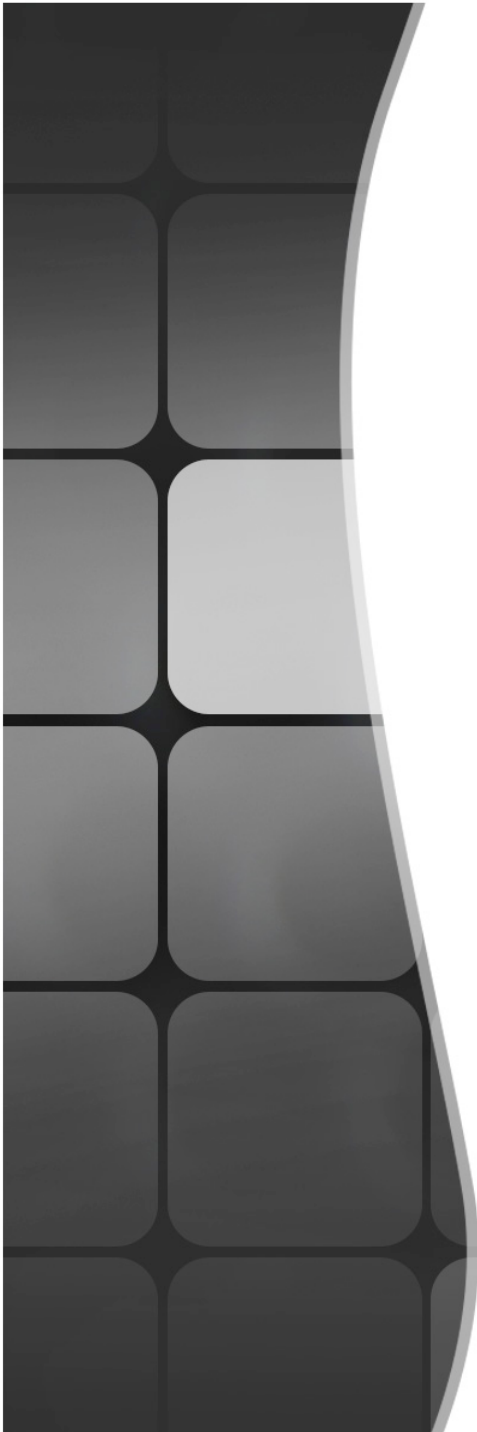
If during the applicable warranty/liability period the consumer experiences any problems with a device that is covered by the warranty as described herein, the consumer may elect any of the following:

- 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 that may be reusable 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 consumer 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 custom made device must be inserted/fitted by a relevant clinical professional; and
- If the manufacturer requests a new impression, but is instructed by the prescribing clinical professional 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 or prescribing clinical professional.



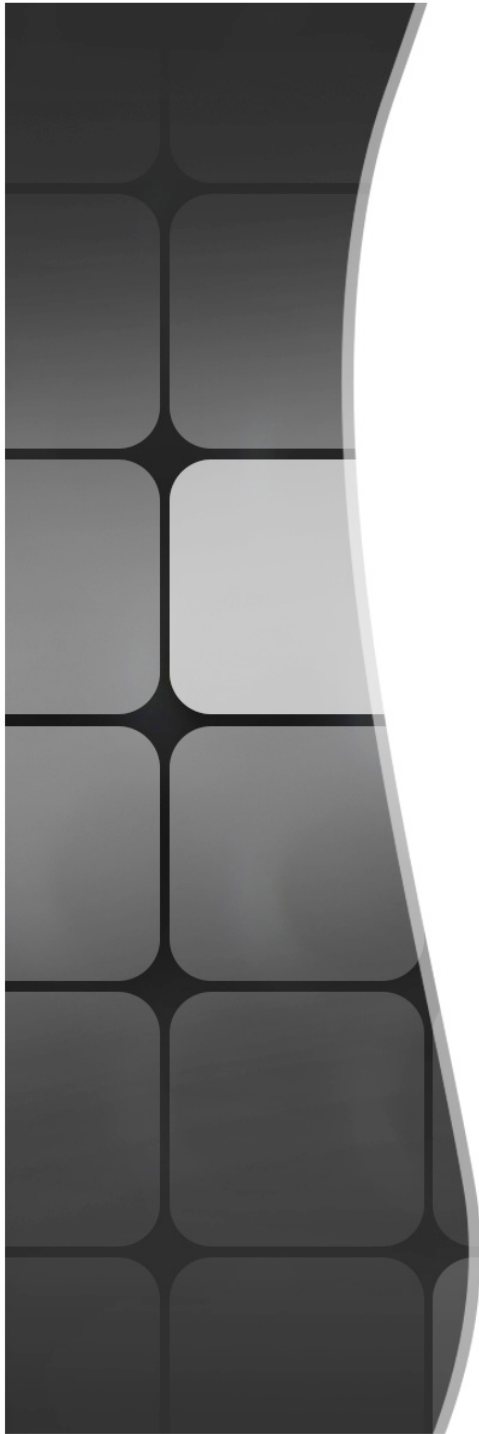
Conditions, which MUST be met for the Warranty/liability to apply:

- All custom made devices or part thereof must be custom fitted by a relevant clinical professional.
- Consumers shall adhere to a six monthly clinical maintenance program in the office of a relevant clinical professional and which must include a full examination and hygiene in inspection.
- The attending relevant clinical professional must document the maintenance schedule on the Certificate of Authenticity after each visit to validate this warranty/liability.
- Any warranty becomes void if the consumer 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.

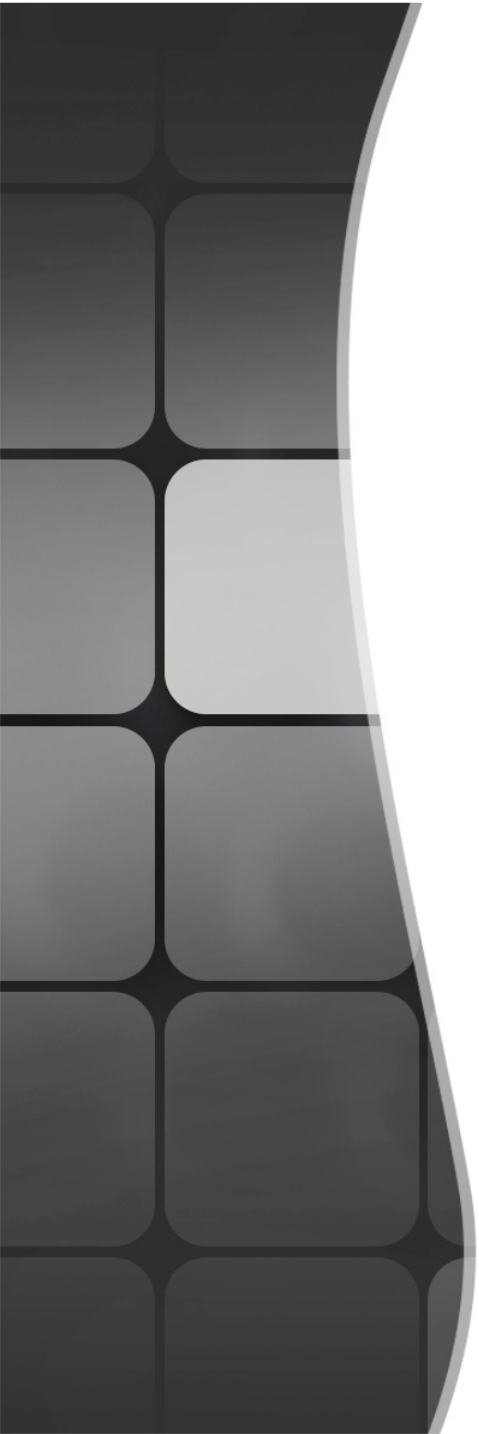


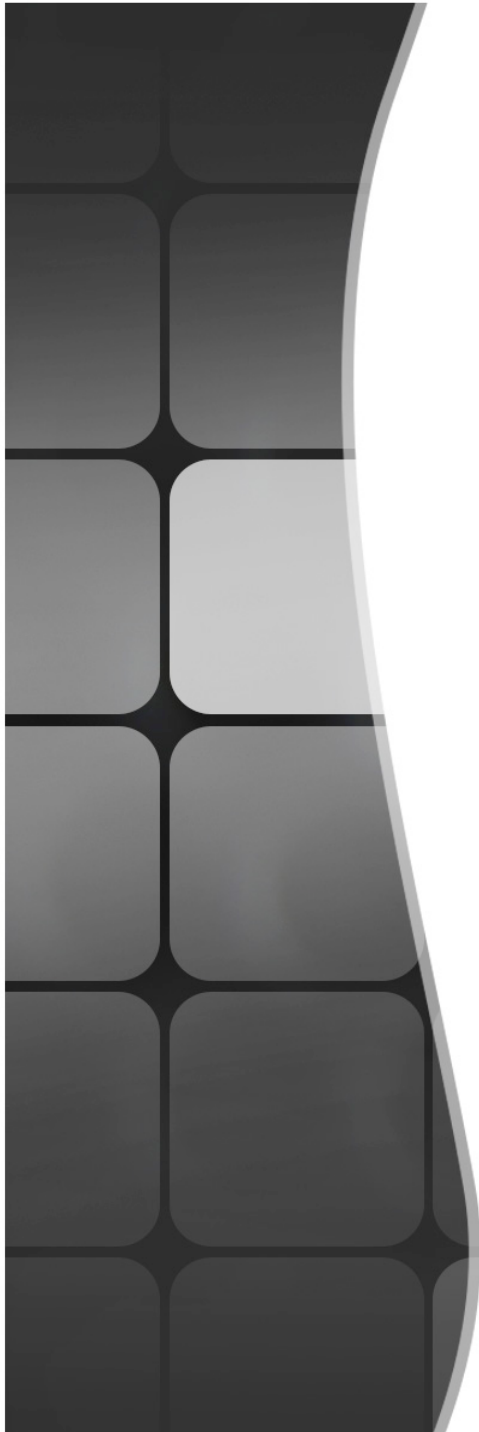
Some very important points

1. You are expected to adhere to the Statement of Liability.
2. Make sure you are reimbursed for the balance.
3. Make sure you fulfill your membership obligation to DENTASA to ensure you are covered by the insurance. Normal public liability insurance is NOT sufficient enough, you need product liability insurance.



4. Communicate to the dentist about any changes to his prescription and make sure you get his consent in writing.
5. Take photos of any defects/problems that you are not comfortable with.
6. Make sure that all documents, (Work order, Certificate of Manufacture, extra notes etc.) everything related to that case is kept in one file, electronically or paper - **This is critical.**

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7. Under this Act, in case of a claim, the onus is on you to prove yourself non negligent. This can only be done by meticulous record keeping. (All remakes irrespective of what they are, must be recorded as new cases and invoiced. Pastel and QuickBooks are good programs to do this with)
 8. The fine payable to the government, and that excludes the patient claim or your legal cost, is R1 million or 10% of your previous years turn over, **WHICH EVER IS GREATER.**



9. It is very important that you read all documents and make sure that you comprehend the content thereof.

(Do not feel embarrassed to ask for help.)

10. DENTASA can only supply you with the tools, its up to you to use them correctly. Make sure you are compliant.

You are on a sinking ship and considering which option to take.
Will you:

- A) Get on the closest boat and just let the tide take you away?
- B) Stay on deck and yell at the fools that they are going the wrong way?
- C) Jump on a boat and grab an oar?



DENTASA is a voluntary association that promotes the interests and needs of the dental technology profession.

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