



*not provided by MMD

ORACOL INSTRUCTIONS FOR USE

Products Covered:

This IFU covers the Oracol (S10) saliva collection device.

Intended Use:

Intended for use in the collection of saliva samples for use in vitro diagnostic tests.

Intended User:

The devices are intended to be used by medical professionals and members of the public.

Patient Population:

Indicated for use in adults and paediatrics.

Packaging & Sterilisation:

The devices are supplied sterile, for single use only. Each device is sterilised via gamma irradiation in accordance with ISO 11137.

Precautions/contraindications:

- Not to be used if the patient has a bleeding gum.
- The device is single use only. Reuse may cause infection.
- Do not use the device if the device is damaged.

Storage:

- To be stored under normal ambient conditions.
- The shelf-life of the product is stated on the label.

Disposal:

Dispose of the device in accordance with local clinical disposal instructions.

Instructions:

Refer overleaf for the instructions

Name and address of manufacturer:

Malvern Medical Developments Ltd.

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**Name and address of EC Rep:**

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