

Device Description	
Product name	Proclinic
Device Category	Temporary root filling material of calcium hydroxide.
Regulation	Council Directive 93/42 EEC concerning medical devices
Classification	Class IIa, rule 7
Product standard(s)	There are no applicable standards for this device.
Description and physical characteristics	<p>Temporary root filling material for conventional endodontic treatment. Used by professional dentist.</p> <p><u>Indications</u> -Pulp capping -Perforation and pulp protection -Insulation</p> <p><u>Composition</u> Calcium Hydroxide 41% Barium Sulphate 8% Ringer Solution pH value 12,4</p>
Safety Data Sheet	Available.
Tox. Properties	Corrosive. Irritating to skin, eye contact may cause serious damage.
Safety information	Presented on package and in instruction for use.
Shelf life	2 years from date of manufacture when stored according to instructions.
Storing	<25°C. Do not refrigerate. Avoid exposure to direct sun light.
Packaging	Syringes of 1,5 ml.

Document	Date	Issued by
Technical Data Sheet - Proclinic	2016-05-03	Agneta Bengtsson