

Instruction for use AlproZyme



CE 0123

Information on processing regarding the workflow and standard operation procedure (SOP) may be maintained at our website: www.alpro-medical.com or can be requested by e-mail: info@alpro-medical.com or by phone: **+49 7725 9392-0**.










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1. User instructions

Please attend to the following instructions in order to guarantee a trouble-free, economic and safe work.

2. Symbols used on product information, labels and instructions for use

	Use before (date of expiry) YYYY-MM
	Batch number XXXXXX (6-digits)
	Please follow the instruction for use
	CE-symbol with Notified Body (0123) for Medical Devices of classes IIa, IIb or III
	Order number
	Manufacturer, ALPRO MEDICAL GmbH, St. Georgen
	Company logo of ALPRO MEDICAL GmbH, St. Georgen

3. Target group

This instruction for use is intended for all users (doctors, dentists and professionals in charge of the processing of medical devices as well as hygiene professionals) in medical and dental facilities.

4. Intended purpose – intended use

Alkaline-enzymatic cleaning granulate for the pre-cleaning and pre-disinfection for the processing of medical and dental instruments, rotating precision instruments and endoscopes. Useable by soaking bath method as well as in ultrasonic devices and washer-disinfectors.

5. Application



Pre-cleaning

- 5.1 Open the bag
- 5.2 Fill the tray (with removable sieve insert) with 2 L **warm** water (20 – 40 °C)
- 5.3 Mix thoroughly bag contents (1 bag) with warm water (warm water is only needed for mixing)
- 5.4 Soak soiled instruments completely and bubble-free
- 5.5 Observe indicated contact time (see table)

Efficacy	Concentration/%	Time/Minutes	
Cleaning	0.5	2	in ultrasonic bath and soaking bath
virucidal high level	0.5 1.0	15 (at 40 °C) 60 (at 30 °C)	ultrasonic bath soaking bath (SOP)

Further processing:

- 5.6 Remove the sieve insert with the instruments (if visibly soiled, repeat point 5.4 and 5.5 where required)
- 5.7 Rinse the instruments with suitable water (e. g. deionized, demineralized/drinking water to avoid lime residues)
- 5.8 For the comprehensive disinfection put the instruments in a suitable instrument disinfection solution (e. g. **BIB forte eco**) or in a washer-disinfector. In this case observe the contact times/hold times of the corresponding manufacturer!
- 5.9 After the contact time (according to manufacturer's instructions) rinse the instruments (manual preparation) with suitable water (see 5.7) and dry them
- 5.10 Check the integrity
- 5.11 According to risk assessment sterilize the instruments, if necessary wrapped


5. Application

Note: Prepare a fresh solution every working day (depending on degree of contamination even more often). Wear protective gloves, an apron impermeable to water and protective glasses!




6. Order data

AlproZyme

REF	Description	
3753	Clinic package 100 bags (10 g each)	 CE 0123

Accessory

REF	Description	
4018	Immersion tray plastic, vol. 4 L for the reprocessing can be reprocessed up to 60°C in the washer-disinfector	

7. Hazard and precautionary statements

Danger. Causes severe skin burns and eye damage. May cause respiratory irritation. Contains Subtilisin. May produce an allergic reaction. Do not breathe dust. Wear protective gloves/protective clothing/eye protection/face protection.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water (or shower).

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

8. Disposal instructions

Prepared solution may be disposed of highly diluted via waste water. The unused product respectively product residues must be disposed of as hazardous waste in compliance with the Directive 2008/98/EC on waste as well as national and regional regulations. If possible leave product in original container. Do not mix with other waste materials. Packaging contaminated with product is considered as hazardous waste and must be disposed of accordingly.

9. Report of incidents

Please report any incident that may occur in connection with the product to:

ALPRO MEDICAL GMBH

and the national authority

Mail: quality@alpro-medical.com

Phone: +49 7725 9392-0



Information on the preparation with regard to the work steps and all current work instructions, safety data sheets, instructions for use etc. can be found on our website: www.alpro-medical.com

If you have any questions, please do not hesitate to contact us at **www.alpro-medical.com** or by phone **+49 7725 9392-0**. You are also welcome to contact our sales representatives by phone or e-mail.