Germo® S.P.A.
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Capitale Sociale € 156.000,00 interamente versato - R.E.A. 497966 Cod. Fisc. e Part. IVA 00772350153 - Iscr. 125750 R.I. Canc. Trib. MI

D-LIZE – TECHNICAL DATASHEET

DERMALIZE D-FENDER

DERMALIZE D-FENDER is a Medical Device CE 0546 class IIa in compliance with Directive 93/42/EEC.

DERMALIZE D-FENDER is a ready-to-use detergent disinfectant of surfaces of non-invasive medical devices (desks, armrests, handles, headrests) of medical, dental or aesthetic surgeries.

DERMALIZE D-FENDER is a broad spectrum disinfectant thanks to the high alcohol content and the presence in the formula of Chlorhexidine diglu-conate and Quaternary Ammonium Salt.

DERMALIZE D-FENDER acts as a bactericide, fungicide, mycobactericide and virucide (including HIV, HBV and HCV) even in the presence of biological material.

It evaporates quickly without leaving streaks.

INSTRUCTIONS FOR USE

Shake well before use and spray DERMALIZE D-FENDER directly on the surface to be treated. Let it act and finally dry it with a cloth or disposable paper. The product is active in five minutes of contact against Gram-positive and Gram-negative bacteria, fungi (yeasts and moulds) and viruses (Adenovirus, HIV, HBV, HCV); against mycobacteria (TBC included) in 60 minutes.

PACKAGING

Internal Code:	Primary packaging:	Secondary packaging:
D750	750 ml bottle	Box with 12 bottles

All primary packaging is made according to the specifications provided by the Pharmacopoeia. The materials do not contain allergenics and are perfectly compatible with all components of the formulation.

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COMPOSITION

100,0 g of product contain: Chlorhexidine Digluconate 0,1 g; Benzalkonium chloride 0,1 g; Ethanol 45,0 g; Isopropyl Alcohol 15,0 g; coformulants; depurated water q.s. to 100,0 g.

PRODUCT FORM

Colourless liquid with characteristic perfume.

ACTIVITY

Chlorhexidine Digluconate in combination with Quaternary Ammonium Compound and the high content of Alcohol guarantees a wide spectrum of action against Gram-positive and Gram-negative bacteria, mycobacteria (TBC included), fungi (yeasts and moulds) and viruses (Adenovirus, HIV, HBV, HCV).

TEST

EN13727; EN13624; EN14348; EN13697; EN14561; EN14562; EN14476.

WARNINGS

Avoid using the product on material sensitive to alcohol. Given the high alcohol content, the product may be unsuitable for sensitive materials, follow the instructions of the manufacturer of the medical device.

VALIDITY

3 years. The indicated period of validity refers to the product stored in its container and properly used and stored.

HOW TO STORAGE

Store in a cool, dry place, away from heat sources.

QUALITY CONTROL

The components (raw materials, containers, labels, etc.) and the processing steps of each lot are regularly and carefully checked internally following the procedures of the Organization Quality Management System certified UNI EN ISO 9001 and UNI EN ISO 13485.

AUTHORIZATIONS

Medical Device CE 0546 class IIa in compliance with Directive 93/42/EEC as amended by Directive 2007/47/EEC.

CONFIDENTIAL INFORMATION FOR PROFESSIONAL USERS