



SAFE DIGITEST

100 SAFETY LANCETS

TECHNICAL INFORMATION

Definition

- Sterile, single-use, Contact activated safety lancet intended for capillary blood sampling.

General features

The device is composed by the following components:

- Complete needle (Stainless steel needle coated with plastic)
- Injection molded housing
- Injection molded shield
- Injection molded cap
- Zinc-plated steel drive/return spring.

Applications

For capillary blood sampling

**Medical device according to the Directive 93/42/EEC
Modified by the directive 2007/47/EC
Implementation with D.L. n°37 del 25-01-2010**

Class IIa

Conformity

- EN ISO 9626
 - EN ISO 11137-2 and ISO/TS 13004
 - EN ISO 10993
 - Quality Management System
- Resistance to corrosion
Sterilization
Biocompatibility
Certified according to EN ISO 13485

Specifiche tecniche

COMPONENT	MATERIAL
Needle	Stainless steel, silicone coated
Shield	Polyethylene with dye
Housing	Polypropylene with dye
Cap	Polypropylene with dye
Drive spring	Zinc coated steel wire
Return spring	Zinc coated steel wire
Complete needle	Polystyrene with dye

Steril	YES
Latex	NO
Validity	5 years
Storage condition	Storage temperature 5°C to 40°C. Relative humidity up to 85%.





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Product sterilization

- Sterilized using irradiation with EN ISO 11137-2.

Biocompatibility

- The product has successfully undergone the biocompatibility tests required by EN ISO 10993-1, for cytotoxicity, hemocompatibility, sensitization, acute systemic toxicity and irritation or intracutaneous reactivity.

Disposal

- In compliance with facility guidelines and local regulation.

Packaging

Labels and/or packages have the following:

Product description
Intended use
CE mark
Manufacturer
Distributor
Use-by date
Lot number
Product REF and Barcode
Caution
IFU
Sterilization method

Packaging material

COMPONENT	MATERIAL
Shelf box of 100 pcs	Carton GC2 Alaska Plus 280 g/m2
Package 20x100 pcs	Carton 5W (EB) ETC 12,1 N

Manufacturer

- HTL-Strefa S.A. ul. Adamówek 7, 95-035 Ozorków, Poland

Assortment

CODE	GAUGE/ PENETRATION DEPTH	BOX	UNIT	PACKAGE
02 047100 000 300	30G x 1.2mm	100 pz	-	20 x 100 pz
02 047100 000 250	25G x 1.5mm	100 pz	-	20 x 100 pz
02 047100 000 210	21G x 1.8mm	100 pz	-	20 x 100 pz
02 047100 001 210	21G x 2.4mm	100 pz	-	20 x 100 pz

Technical Director
PIKDARE S.p.A.
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Medical Devices Department
Technical Director





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