


<h2>Peha-instrument: Irrigating cannula</h2>		Spec.-No.: D 6.2006	
		Department: CMO-DOE	
		Date: 2013-11-15	

1. General Product Description

The Peha-instrument Irrigating cannulas are sterile single use surgical instruments, made of stainless steel, marked with single use symbol according to DIN EN ISO 15223-1 on the packaging of the instruments.

Peha-instrument Irrigating cannulas carry the CE mark according to EU directive 93/42/EEC for medical devices. The products are classified as Class IIa medical device.

A conformity assessment has been performed for Peha-instrument Irrigating cannulas and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use and effectiveness of Peha-instrument Irrigating cannulas, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

The indication of the Peha-instrument Irrigating Cannulas are listed below:

Name	Intended use
Irrigating cannula, 8,1 cm, 18G	cannula for wash up and out the wound and hurt for single use

The instruments are intended to be used only once (SINGLE USE). They shall not be re-sterilised.


3. Presentation

Content:


- Single instrument in sterile peel pouch (Hard-Foil /Tyvek)
- Single packed instruments in dispenser: 25 pieces/dispenser
- 2 dispensers / transport carton

Sizes:

- Dispenser: 205 x 103 x 137 mm (L x B x H)
- Transport carton: 224 x 246 x 156 mm (L x B x H)

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4. Product Characteristics

Design	
Irrigating cannula 8,1 cm, 18G	
Material	
Austenitic stainless steel	AISI 304 (according to ASTM F 889-07)
Polymer (polycarbonate)	Makrolon® 2858
Sterilisation	
Method	EO-sterilisation

5. Product Requirements

The Peha-instrument Irrigating cannulas fulfil the essential requirements of the EU directive 93/42/EEC for medical devices.

6. Labelling

Lot-No. with 9-digit code:

e.g.: x xxx xx xxx

LOT	x	xxx	xx	xxx
	year	internal data	week of production	internal data


Expiry date: 6-digit code:

e.g.: ⌚ 2018 01
 year month

Shelf life: 5 years

EAN 128 etiquette on dispenser and transport carton.

		<h1>Technical Data Sheet</h1>
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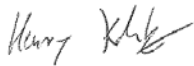
7. Packaging

Peha-instrument Irrigating cannulas are packaged in peel containers and dispensers. The dispensers are packed in transport cardboard boxes according to DIN which are sealed with adhesive tapes. Packaging onto euro pallet.

Date: 2013-11-15

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i.A.



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