

TECHNICAL DATASHEET

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Tubing Sets Single Pump System Single Use MD0105.02

General Information

Intended use:	The product is intended to be used during surgical procedures in the anterior and posterior eye segment for: <ul style="list-style-type: none">- transportation of aspirated fluids, tissues, and gases- supply of irrigation fluid to maintain the intraocular pressure
For use with device:	The medical device is used together with the following Oertli products: <ul style="list-style-type: none">- Faros surgery systems (MD1105.03)- CataRhex-Family surgery systems (MD1105.04, MD1105.07)- Phaco handpieces reusable (MD0105.111)- I/A instruments single use (MD0105.31)- I/A instruments reusable (MD0105.113)- I/A coaxial handpiece reusable (MD0105.115)- vitrectomy cutter single use (MD0105.42)- cutting instruments reusable (MD0105.114)- air delivery line single use (MD0105.74)- active infusion set single use (MD0105.75)- Infusion set single use (MD0105.09)- waste container (MD0100.03)- drainage bag (MD0100.04)
Notified Body:	DQS Medizinprodukte GmbH, 60433 Frankfurt am Main, Germany
Certification:	CE0297
Classification:	Class IIa according Rule 2.1
GMDN-Code:	47625
Manufacturer:	Oertli Instrumente AG, 9442 Berneck, Switzerland

Technical Data

Type of use:	Single use
Processing instructions:	not applicable
Sterilization method:	Ethylenoxid (ETO) sterilization
Shelf life:	3 years
Instructions for use:	TN999080
Packaging:	Sterile barrier system: PETG blister with Tyvek seal Protective packaging: cardboard box
Packaging size:	1 cardboard box contains 10 products
Package contents:	See at the section "List of content" for the specific content of each article of this product group

DESCRIPTION OF MODEL

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Material:

Part	Direct patient contact	In-direct patient contact	No patient contact
Coupling part and parts within	-	Polymer (e.g. PC, PP, PSU, Silicone)	Stainless steel Polymer (e.g. ABS)
Luer	-	Polymer (e.g. PA, PC, PP)	-
Tubing	-	Polymer (e.g. PVC, silicone)	-

Table 1: material specification

PVC: Yes

Phthalates: No

Animal origin: No

List of content

Article Number	VV621010
Description	Tubing set for Faros/CataRhex 3/Swisstech, sterile/single use, box of 10
Packaging	Sterile barrier system: Thermoplastic blister-shell with Tyvec seal Protective packaging system: Outer: cardboard box
Dimensions	Tubing set with tubes: Coupling part: L/W/H: 86x50x45 mm Tubes length: < 1800 mm



Table 2: model description

DESCRIPTION OF MODEL

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Article Number	VV621010A
Description	Tubing set for Faros/CataRhex 3/Swisstech, sterile/single use, box of 10
Packaging	Sterile barrier system: Thermoplastic blister-shell with Tyvec seal Protective packaging system: Outer: cardboard box
Dimensions	Tubing set with tubes: Coupling part: L/W/H: 86x50x45 mm Tubes length: < 1800 mm Infusion set: L: < 1700 mm Drainage bag: L/W: 160 x 270 mm Remote control cover:

Table 3: model description



Article Number	VV621010B
Description	Tubing set for Faros/CataRhex 3/Swisstech, sterile/single use, box of 10
Packaging	Sterile barrier system: Thermoplastic blister-shell with Tyvec seal Protective packaging system: Outer: cardboard box
Dimensions	Tubing set with tubes: Coupling part: L/W/H: 86x50x45 mm Tubes length: < 1800 mm Infusion set: L: < 1700 mm Drainage bag: L/W: 160 x 270 mm

Table 4: model description



DESCRIPTION OF MODEL

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Article Number	Description	Tubing set single pump single use	Infusion set	Drainage bag	Remote control cover
VV621010	Tubing set Faros/CataRhex 3/Swisstech	✓	-	-	
VV621010A	Tubing set Faros/CataRhex 3/Swisstech	✓	✓	✓	✓
VV621010B	Tubing set Faros/CataRhex 3/Swisstech	✓	✓	✓	

Table 5: model description