

8. Declaration of Conformity

DECLARATION OF CONFORMITY

optimed Medizinische Instrumente GmbH
Ferdinand-Porsche-Straße 11
76275 Ettlingen

hereby declares in its own responsibility that

VARIOTIP
VARIOTIP PREMIUM

Order codes:
*Please refer to the annexed article range
of TD1015_1.1.7, Rev. 1*

is a Class Is medical device
reviewed in accordance with Annex II excluding section (IV)

0124

DEKRA Certification GmbH
Handwerkstrasse 15
D-70565 Stuttgart

conforming to the relevant provisions of the Directive 93/42/EEC.
This Declaration of Conformity is valid until 26.05.2024.
The validity corresponds to the validity of the CE-certificate number 50066-16-08.

Ettlingen, 25.06.2021



Frank Wohkittel

Head of Regulatory Affairs



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1.1.7 Complete List of the Various Configurations and Variants

Extension	Order Code	Specification
_VTS	3105-0010	VarioTip Ureteral Catheter, tip: 30° angled, central opening D: 5 CH (1.67 mm), L: 70 cm
_VTS	3105-0050	VarioTip Ureteral Catheter, tip: 30° angled, central opening D: 5 CH (1.67 mm), L: 70 cm
_VTP	3331-0120	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, no side holes D: 3 CH (1.00 mm), L: 70 cm
_VTP	3331-1100	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, 1 side hole D: 4 CH (1.33 mm), L: 70 cm
_VTP	3331-1110	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, 2 side holes D: 4 CH (1.33 mm), L: 70 cm
_VTP	3331-1120	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, no side hole D: 4 CH (1.33 mm), L: 70 cm
_VTP	3331-2100	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, 1 side hole D: 5 CH (1.67 mm), L: 70 cm
_VTP	3331-2110	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, 2 side holes D: 5 CH (1.67 mm), L: 70 cm
_VTP	3331-2120	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, no side hole D: 5 CH (1.67 mm), L: 70 cm
_VTP	3331-3100	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, 1 side hole D: 6 CH (2.00 mm), L: 70 cm
_VTP	3331-3110	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, 2 side holes D: 6 CH (2.00 mm), L: 70 cm
_VTP	3331-3120	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, no side hole D: 6 CH (2.00 mm), L: 70 cm
_VTP	3331-4110	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, 2 side holes D: 7 CH (2.33 mm), L: 70 cm
_VTP	3331-4120	VarioTip Premium Ureteral Catheter, tip: radiopaque, straight, cylindrical tip, central opening, no side hole D: 7 CH (2.33 mm), L: 70 cm

Summary Technical Documentation

TD1015_1.1.7

Revision:1

Approved on: 14.10.2014

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_VTP	3333-0120	VarioTip Premium Ureteral Catheter, tip: radiopaque, curved, cylindrical tip, central opening, no side hole D: 3 CH (1.00 mm), L: 70 cm
_VTP	3333-1100	VarioTip Premium Ureteral Catheter, tip: radiopaque, curved, cylindrical tip, central opening, 1 side hole D: 4 CH (1.33 mm), L: 70 cm
_VTP	3333-1110	VarioTip Premium Ureteral Catheter, tip: radiopaque, curved, cylindrical tip, central opening, 2 side holes D: 4 CH (1.33 mm), L: 70 cm
_VTP	3333-1120	VarioTip Premium Ureteral Catheter, tip: radiopaque, curved, cylindrical tip, central opening, no side hole D: 4 CH (1.33 mm), L: 70 cm
_VTP	3333-2100	VarioTip Premium Ureteral Catheter, tip: radiopaque, curved, cylindrical tip, central opening, 1 side hole D: 5 CH (1.67 mm), L: 70 cm
_VTP	3333-2110	VarioTip Premium Ureteral Catheter, tip: radiopaque, curved, cylindrical tip, central opening, 2 side holes D: 5 CH (1.67 mm), L: 70 cm
_VTP	3333-2120	VarioTip Premium Ureteral Catheter, tip: radiopaque, curved, cylindrical tip, central opening, no side hole D: 5 CH (1.67 mm), L: 70 cm
_VTP	3333-2150	VarioTip Premium Ureteral Catheter, tip: radiopaque, 30 ° angled, central opening, no side hole D: 5 CH (1.67 mm), L: 70 cm
_VTP	3333-3110	VarioTip Premium Ureteral Catheter, tip: radiopaque, curved, cylindrical tip, central opening, 2 side holes D: 6 CH (2.00 mm), L: 70 cm
_VTP	3333-3120	VarioTip Premium Ureteral Catheter, tip: radiopaque, curved, cylindrical tip, central opening, no side hole D: 6 CH (2.00 mm), L: 70 cm
_VTP	3333-4120	VarioTip Premium Ureteral Catheter, tip: radiopaque, curved, cylindrical tip, central opening, no side hole D: 7 CH (2.33 mm), L: 70 cm

Key:

_VTS	VarioTip Standard
_VTP	VarioTip Premium