



Konformitätserklärung / Declaration of Conformity

Form version 4.10

Hersteller/Manufacturer:

W.O.M. WORLD OF MEDICINE GmbH
Salzufer 8, 10587 Berlin, Germany

erklärt in alleiniger Verantwortung, dass die Medizinprodukte
declares on its sole responsibility that the medical devices

wiederverwendbare und einmal verwendbare Schlauchsets /
reusable and disposable tube sets

(siehe Anhang) / (see Attachment)

ab Herstellungsdatum
starting manufacturing date

2014-09

in Erfüllung der und in Übereinstimmung mit den anwendbaren Normen
in fulfillment of and in compliance with the applicable standards

die Grundlegenden Anforderungen der Richtlinie des Rates der Europäischen Gemeinschaft über
Medizinprodukte
fulfills the Essential Requirements and is in conformity with the European directive on medical devices

93/42/EWG in der Fassung vom 20.03.2010 nach Anhang II, ohne Abschnitt 4 /
93/42/EEC version dated the 20.03.2010 according to Annex II, excluding Section 4

erfüllt.

Diese Erklärung erlischt zum 26.05.2024 / This declaration expires on the 26.05.2024.

Benannte Stelle der W.O.M. WORLD OF MEDICINE GmbH ist
The notified body of W.O.M. WORLD OF MEDICINE GmbH is
TÜV Rheinland LGA Products GmbH, Tillystr. 2, 90431 Nürnberg, Germany, code 0197.

Berlin, 17.03.2020


Dr. Sören Markworth
Head of Regulatory Affairs
W.O.M. WORLD OF MEDICINE GmbH



A Novanta Company

Anhang zu der Konformitätserklärung vom 17.03.2020
Appendix to the Declaration of Conformity issued on the 17.03.2020

Diese Erklärung gilt für folgende Produkte:
This Declaration of Conformity covers the following products:

Artikelnr./ Article No	Beschreibung	Description
Tube sets for Insufflation single-use		
Class IIa***		
Z1422-01	Schlauchset für Insufflation, einmalverwendbar, für F25/F30/F40/F102/F103/F104/F128/FP130	Tube set for insufflation, single-use, for F25/F30/F40/F102/F103/F104/F128/FP130
Z1461-39	Einmalverwendbares Schlauchset "Heated tube set with Real-Time Pressure Sensing (RTP)" für PNEUMO SURE high flow insufflator	Disposable tube set "Heated tube set with Real-Time Pressure Sensing (RTP)" for PNEUMO SURE high flow insufflator
Z1462-39	Einmalverwendbares Schlauchset "High Flow tube set with Real-Time Pressure Sensing (RTP)" für PNEUMO SURE high flow insufflator	Disposable tube set "High Flow tube set with Real-Time Pressure Sensing (RTP)" for PNEUMO SURE high flow insufflator
Z1463-39	Einmalverwendbares Schlauchset "High Flow II tube set" für PNEUMO SURE high flow insufflator	Disposable tube set "High Flow II tube set" for PNEUMO SURE high flow insufflator
Tube sets for Insufflation reusable		
Class: IIa***		
Z0452-01	Schlauchset für Insufflation, wiederverwendbar, für F20/F25/F30/F40/F102/F104/F128/FP130/FM134 (Stryker Nr.: 0620240223)	Tube set for insufflation, reusable, for F20/F25/F30/F40/F102/F104/F128/FP130/FM134 (Stryker No.: 0620240223)
Z1415-01	Heizschlauchset für Insufflation, wiederverwendbar, für F20/F25/F30/F40/F103/F104	Heating tube set for insufflation, reusable, for F20/F25/F30/F40/F103/F104
Z1460-39	Heizschlauchset für Insufflation, wiederverwendbar, für PNEUMO SURE high flow insufflator	Heating tube set for insufflation, reusable, for PNEUMO SURE high flow insufflator
Tube sets for irrigation single-use		
Class: IIa***		
Z0449-01	Schlauchset für Spülung, einmalverwendbar, für HM2/H100/H108/AM3/AM4/AM6/A106/P05/P06/P100/P101/V100	Tube set for irrigation, single-use, for HM2/H100/H108/AM3/AM4/AM6/A106/P05/P06/P100/P101/V100
Z1409-39	Inflow- und Outflowset für FLUID SAFE Fluid Management System	Integrated Tubing for FLUID SAFE Fluid Management System
Z1420-39	Schlauchset für A06/A07/P102/FLOCONTROL arthroscopy pump FLUID SAFE Fluid Management System	Tube set for A06/A07/P102/FLOCONTROL arthroscopy pump FLUID SAFE Fluid Management System



A Novanta Company

Artikelnr./ Article No	Beschreibung	Description
Z1421-39	Schlauchset mit Safe Lock für A06/A07/P102/ FLOCONTROL arthroscopy pump FLUID SAFE Fluid Management System	Tube set with Safe Lock for A06/A07/P102/ FLOCONTROL arthroscopy pump FLUID SAFE Fluid Management System
Z1424-01	Schlauchset für Spülung, einmalverwendbar, für HM2/H100/ H108/AM3/AM4/AM6/A106/P05/P06/ P100/P101/V100	Tube set for irrigation, single-use, for HM2/H100/H108/AM3/AM4/AM6/A106/P05 /P06/P100/P101/V100
Z1442-39	Inflow- und Outflowset für FLOCONTROL arthroscopy pump	Integrated Tubing for FLOCONTROL arthroscopy pump
Z1443-39	Tagesset besteht aus: Pumpenschlauch 1x und Patientenschlauch 10x für FLOCONTROL arthroscopy pump	Daily set consists of: Pump tube 1x and patient tube 10x for FLOCONTROL arthroscopy pump
Z1444-39	Tagesset besteht aus: Pumpenschlauch 1x und Patientenschlauch 10x für FLOCONTROL arthroscopy pump	Daily set consists of: Pump tube 1x and patient tube 10x for FLOCONTROL arthroscopy pump
Z1446-39	Pumpenschlauch für Z1443-39 FLOCONTROL arthroscopy pump	Pump tube for Z1443-39 FLOCONTROL arthroscopy pump
Z1447-39	Pumpenschlauch für Z1444-39 FLOCONTROL arthroscopy pump	Pump tube for Z1444-39 FLOCONTROL arthroscopy pump
Z1450-39	Schlauchset für FLOSTEADY arthroscopy pump	Tube Set for FLOSTEADY arthroscopy pump
Z1451-39	Schlauchset mit Safe Lock für FLOSTEADY arthroscopy pump	Tube set with Safe Lock for FLOSTEADY arthroscopy pump
Z1452-39	Tagesset besteht aus: Kassettenschlauch 1x und Patientenschlauch 10x FLOSTEADY arthroscopy pump	Day set consists of: Cassette tube 1x and patient tube 10x for FLOSTEADY arthroscopy pump
Z1453-39	Tagesset besteht aus: Kassettenschlauch 1x und Patientenschlauch 10x FLOSTEADY arthroscopy pump	Day set consists of: Cassette tube 1x and patient tube 10x for FLOSTEADY arthroscopy pump
Z1454-39	Kassettenschlauch für Z1452-39 FLOSTEADY arthroscopy pump	Cassette tube for Z1452-39 FLOSTEADY arthroscopy pump
Z1455-39	Kassettenschlauch mit Safe Lock für Z1453-39 FLOSTEADY arthroscopy pump	Cassette tube with Safe Lock for Z1453-39 FLOSTEADY arthroscopy pump

Tube sets for irrigation reusable

Class: IIa***

Z0454-01	Schlauchset für Spülung, wiederverwendbar, für HM2/H100/ H108/AM3/AM4/AM6/A106/P05/P06/ P100/P101/V100	Tube set for irrigation, reusable, for HM2/H100/H108/AM3/AM4/AM6/A106/P05 /P06/P100/P101/V100
Z1428-39	Schlauchset, wiederverwendbar für A06/A07/P102/ FLOCONTROL arthroscopy pump FLUID SAFE Fluid Management System	Tube set, reusable for A06/A07/P102/ FLOCONTROL arthroscopy pump FLUID SAFE Fluid Management System

Tube sets for suction

Class: Is**

Z1406-01	Schlauchset für Absaugung, einmalverwendbar, für HM2/H100/H108	Tube set for suction, single-use, for HM2/H100/H108
Z1406-39	Schlauchset für FLUID SAFE Fluid Management System	Tube Set for FLUID SAFE Fluid Management System



A Novanta Company

Artikelnr./ Article No	Beschreibung	Description
Tube sets for vacuum		
Class: I*		
Z1426-01	Schlauchset für Vakuum, wiederverwendbar, für P06/P100/P101/P102	Tube set for vacuum, reusable, for P06/P100/P101/P102

**Zubehör der Klasse I erfüllt die Grundlegenden Anforderungen der Richtlinie 93/42/EWG vom 20.03.2010 nach Anhang VII /
Class I accessories fulfill the Essential Requirements of Directive 93/42/EEC dated the 20.03.2010 according to Annex VII*

***Zubehör der Klasse Is erfüllt die Grundlegenden Anforderungen der Richtlinie 93/42/EWG vom 20.03.2010 nach Anhang VII
und Anhang II, ohne Abschnitt 4 /
Class I accessories fulfill the Essential Requirements of Directive 93/42/EEC dated the 20.03.2010 according to Annex VII and
Annex II, excluding Section 4*

****Zubehör der Klasse IIa und IIb erfüllt die Grundlegenden Anforderungen der Richtlinie 93/42/EWG vom 20.03.2010 nach
Anhang II, ohne Abschnitt 4 /
Class IIa and IIb accessories fulfill the Essential Requirements of Directive 93/42/EEC dated the 20.03.2010 according to Annex
II, excluding Section 4*