



# EG-ZERTIFIKAT

(Vollständiges Qualitätssicherungssystem)



Zaświadcza się, że firma

## ORIPLAST GmbH

Hermannstraße 150  
66538 Neunkirchen  
Deutschland

ustanowiła i stosuje kompletny system zapewnienia jakości na każdym etapie od projektu do kontroli produktu końcowego.

Udokumentowany raportem audyt przeprowadzony przez DQS Medizinprodukte GmbH potwierdził, że ten system zapewnienia jakości spełnia wymagania zgodnie z

### Aneks II – z wyłączeniem sekcji 4 Dyrektywy Rady 93/42/EWG w sprawie wyrobów medycznych

spełnionych w odniesieniu do następujących wyrobów medycznych:

Produkt	Klasa
Sterylny artykuły jednorazowego użytku do infuzji, transfuzji, Dostarczanie tlenu do nosa i odsysanie chirurgiczne	Is / IIa
Drenaż	IIa
Odprowadzenie moczu	Is / Im

Producent podlega nadzorowi zgodnie z aneksem II, rozdział 5. Oznaczenie CE z numerem identyfikacyjnym jednostki notyfikowanej (0297) może być umieszczane na produktach wymienionych w certyfikacie. W celu wprowadzenia do obrotu urządzeń klasy III a

Konieczne jest badanie projektu produktu WE zgodnie z aneksem II, sekcja 4. Dla produktów klasy I(s) (I(s) = produkty klasy I wprowadzane do obrotu w stanie sterylnym) certyfikat ogranicza się wyłącznie do produkcji w związku ze sterylizacją i utrzymaniem sterylności. Dla wyrobów klasy I(m) (I(m) = wyroby klasy I z funkcją pomiarową) certyfikat ogranicza się wyłącznie do produkcji w związku ze zgodnością wyrobów z wymaganiami metrologicznymi.

Nr certyfikatu. 346155 MR2  
ID certyfikatu 170775779  
Ważny od 2021-04-19  
Ważny do 2024-01-09  
Frankfurt nad Menem 2021-04-19

## DQS Medizinprodukte GmbH

Podpis nieczytelny

Podpis nieczytelny

Sigrid Uhlemann  
Dyrektor Zarządzający

dr Thomas Feldmann  
Kierownik jednostki  
certyfikującej

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)

DQS Medizinprodukte GmbH jest jednostką notyfikowaną zgodnie z dyrektywą Rady 93/42/EWG w sprawie wyrobów medycznych o numerze identyfikacyjnym 0297.



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Hiermit wird bescheinigt, dass das Unternehmen

## ORIPLAST GmbH

Hermannstraße 150  
66538 Neunkirchen  
Deutschland

ein vollständiges Qualitätssicherungssystem für jede Phase von der Auslegung bis zur Endkontrolle der Produkte eingeführt hat und anwendet.

Durch ein Audit, dokumentiert in einem Bericht, durchgeführt von DQS Medizinprodukte GmbH, wurde der Nachweis erbracht, dass dieses Qualitätssicherungssystem die Forderungen gemäß

## Anhang II – ohne Abschnitt 4 der Richtlinie 93/42/EWG des Rates über Medizinprodukte

bezüglich folgender Medizinprodukte erfüllt:

Produkt	Klasse
Sterile Einmalartikel für die Infusion, Transfusion, Nasale Sauerstoffverabreichung und OP-Absaugung	Is / IIa
Drainage	IIa
Harnableitung	Is / Im

Der Hersteller unterliegt der Überwachung nach Anhang II, Abschnitt 5. Die CE-Kennzeichnung mit der Kennnummer der Benannten Stelle (0297) darf an den auf dem Zertifikat gelisteten Produkten angebracht werden. Für das Inverkehrbringen von Klasse III Produkten ist eine EG Produktauslegungsprüfung nach Anhang II, Abschnitt 4 notwendig. Das Zertifikat beschränkt sich für Produkte der Klasse I(s) (I(s) = Produkte der Klasse I die in sterilem Zustand in Verkehr gebracht werden) ausschließlich auf die Herstellung im Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität. Das Zertifikat beschränkt sich für Produkte der Klasse I(m) (I(m) = Produkte der Klasse I mit Messfunktion) ausschließlich auf die Herstellung im Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.

Zertifikat-Registrier-Nr. 346155 MR2  
Zertifikat-ID 170775779  
Gültig ab 2021-04-19  
Gültig bis 2024-01-09  
Frankfurt am Main, den 2021-04-19

## DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Geschäftsführerin

Dr. Thomas Feldmann  
Leiter der Zertifizierungsstelle

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)

Die DQS Medizinprodukte GmbH ist Benannte Stelle gemäß der Richtlinie 93/42/EWG des Rates über Medizinprodukte mit der Kennnummer 0297.



# EC-Declaration of Conformity

ORIPLAST GmbH  
Hermannstraße 150 Industriegebiet  
66538 Neunkirchen  
Deutschland

Declare on sole responsibility that the following products

## Wound-Secretion-Management

- Class IIa -

meet all provisions of Directive 93/42/EEG Annex II and is eligible to carry the mark



The individual products with their article numbers are listed in the appendix.

Notified Body:

DQS Medizinprodukte GmbH  
August-Schanz-Straße 21  
D – 60433 Frankfurt am Main

Expiry date: bis 09.01.2024

Neunkirchen, den 12.02.2021  
Ort, Datum

A handwritten signature in blue ink, reading 'A. Sauerwein'.

General Manager: Alexander Sauerwein

# Annex

## Declaration of Conformity

DMF A  
(Wound-Secretion-  
Management)  
Class IIa

DMF	REF	Article	Risk
			Class
A	VK00011	Silicone flat drain length 1000 mm, width 7 mm, height 4 mm, 3/4 perforated	IIa
A	VK00012	Silicone flat drain length 1000 mm, width 10 mm, height 4 mm, 3/4 perforated	IIa
A	VK00013	Silicone flat drain length 1000 mm, width 7 mm, height 4 mm, full perforated	IIa
A	VK00014	Silicone flat drain length 1000 mm, width 10 mm, height 4mm, full perforated	IIa
A	VK00017	Silicone round drain 1300 mm, FG 15, 230 mm cross-perforated, Luer plug, X-ray contrast line	IIa
A	VK00021	Suction set with flat drain suction reservoir 1000 mm <sup>3</sup> ; flat drain width 10 mm, height 4 mm, 3/4-perforated	IIa
A	VK00022	Suction set with flat drain suction reservoir volume 1000 mm <sup>3</sup> ; flat drain width: 7 mm, height 4 mm, full perforated	IIa
A	VK00023	Suction set with flat drain suction reservoir volume 1000 mm <sup>3</sup> ; flat drain width 10 mm, height 4 mm, full perforated	IIa
A	VK00024	Silicone capillary drain length 300 mm, width 6 mm, X-ray contrast line (Penrose)	IIa
A	VK00025	Silicone capillary drain length 300 mm, width 8 mm, X-ray contrast line (Penrose)	IIa
A	VK00026	Silicone capillary drain Length 300 mm, width 10 mm, X-ray contrast line (Penrose)	IIa
A	VK00027	Silicone capillary drain length 100 mm, width 10 mm, X-ray contrast line (Penrose)	IIa
A	VK00028	Silicone capillary drain length 300 mm, width 12 mm, X-ray contrast line (Penrose)	IIa
A	VK00036	Redon drain 800 mm, FG 8, 140 mm middle perforated, X-ray contrast line	IIa
A	VK00045	Redon drain 800 mm, FG 10, 140 mm cross-perforated, X-ray contrast line	IIa
A	VK00046	Redon drain 800 mm, FG 12, 140 mm cross-perforated, X-ray contrast line	IIa
A	VK00051	Redon drain 800 mm, FG 10, 140 mm cross-perforated, X-ray contrast line; needle	IIa
A	VK00052	Redon drain 800 mm, FG 12, 140 mm cross-perforated, X-ray contrast line; needle 200 mm	IIa
A	VK00058	Redon drain 500 mm, FG 6, 70 mm perforated, X-ray contrast line	IIa
A	VK00059	Redon drain 500 mm, FG 6, 140 mm perforated, X-ray contrast line	IIa
A	VK00067	Redon drain 500 mm, FG 8, 70 mm cross-perforated, X-ray contrast line	IIa
A	VK00068	Redon drain 500 mm, FG 8, 140 mm cross-perforated, X-ray contrast line	IIa
A	VK00069	Redon drain 500 mm, FG 8, 140 mm cross-perforated, X-ray contrast line; needle 200 mm	IIa
A	VK00072	Redon drain 500 mm, FG 10, 70 mm cross-perforated, X-ray contrast line	IIa
A	VK00073	Redon drain 500 mm, FG 10, 140 mm cross-perforated, X-ray contrast line	IIa
A	VK00074	Redon drain 500 mm, FG 10, 140 mm cross-perforated, X-ray contrast line; needle 195 mm	IIa
A	VK00076	Redon drain 500 mm, FG 12, 70 mm cross-perforated, X-ray contrast line	IIa
A	VK00077	Redon drain 500 mm, FG 12, 140 mm cross-perforated, X-ray contrast line	IIa
A	VK00078	Redon drain 500 mm, FG 12, 140 mm cross-perforated, X-ray contrast line; needle 200 mm	IIa
A	VK00079	Redon drain 500 mm, FG 14, 70 mm cross-perforated, X-ray contrast line	IIa
A	VK00080	Redon drain 500 mm, FG 14, 140 mm cross-perforated, X-ray contrast line	IIa
A	VK00081	Redon drain 500 mm, FG 14, 140 mm cross-perforated, X-ray contrast line; needle 200 mm	IIa
A	VK00082	Redon drain 500 mm, FG 16, 70 mm cross-perforated, X-ray contrast line	IIa
A	VK00083	Redon drain 500 mm, FG 16, 140 mm cross-perforated, X-ray contrast line	IIa

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A	VK00084	Redon drain 500 mm, FG 16, 140 mm cross-perforated, X-ray contrast line; needle 200 mm	IIa
A	VK00085	Redon drain 700 mm, FG 8, 70 mm cross-perforated, X-ray contrast line	IIa
A	VK00086	Redon drain 500 mm, FG 18, 70 mm cross-perforated, X-ray contrast line	IIa
A	VK00087	Redon drain 500 mm, FG 18, 140 mm cross-perforated, X-ray contrast line	IIa
A	VK00088	Redon drain 500 mm, FG 18, 140 mm cross-perforated, X-ray contrast line; needle 200 mm	IIa
A	VK00090	ORIFLEX IV replacement bottle 400 ml	IIa
A	VK00098	Redon drain 500 mm, FG 6, 70 mm perforated, X-ray contrast line; needle 60 mm	IIa
A	VK00099	Redon drain 500 mm, FG 8, 70 mm cross-perforated, X-ray contrast line; needle 60	IIa
A	VK00100	Mini Pack bellow 150 ml, cut down connector, Luer-Rekord-Steck; silicone drain 500 mm, 10 FG, cross-perforation 140 mm, X-ray contrast line	IIa
A	VK00103	Low Vacuum System bellow 350 ml, 1080 mm, cut down connector, non-return valve, QL connection; drain 500 mm, 10 FG, cross-perforation 140 mm, X-ray	IIa
A	VK00134	Pleura puncture set 1500 ml, NRV, 900 mm, three-way stopcock blue, syringe 50 ml, injection needle 14 G	IIa
A	VK00136	Pleura puncture set 2000 ml, NRV, bottom drain valve, 900 mm, three-way stopcock blue, LL male, syringe 50 ml; injection needle 14 G	IIa
A	VK00140	Pleura puncture set 1500 ml, NRV, 900 mm, three-way stopcock blue detachable, LL male, syringe 50 ml; injection needle 14 G	IIa
A	VK00144	Silicone round drain 500 mm, FG 16, 5 lateral eyes, central opening, X-Ray contrast	IIa
A	VK00145	Silicone round drain 500 mm, FG 15, 5 lateral eyes, central opening, X-Ray contrast	IIa
A	VK00146	Silicone round drain 800 mm, FG 15, 240 mm cross-perforated, X-Ray contrast line	IIa
A	VK00148	Silicone round drain 250 mm, FG 12, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00149	Silicone round drain 500 mm, FG 12, 5 lateral eyes, central opening, X-Ray contrast	IIa
A	VK00150	Silicone round drain 500 mm, FG 24, 2 lateral eyes, central opening, X-ray contrast	IIa
A	VK00152	Silicone round drain 500 mm, FG 10, 70 mm cross-perforated, central opening, X-ray contrast line	IIa
A	VK00153	Silicone round drain 500 mm, FG 10, 140 mm cross-perforated, central opening, X-ray contrast line	IIa
A	VK00155	Silicone round drain 500 mm, FG 8, 70 mm cross-perforated, central opening, X-ray contrast line	IIa
A	VK00156	Silicone round drain 250 mm, FG 18, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00157	Silicone round drain 500 mm, FG 18, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00158	Silicone round drain 250 mm, FG 21, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00159	Silicone round drain 500 mm, FG 21, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00160	Silicone round drain 250 mm, FG 24, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00161	Silicone round drain 500 mm, FG 24, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00162	Silicone round drain 500 mm, FG 25, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00164	Silicone round drain 500 mm, FG 27, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00165	Silicone round drain 600 mm, FG 27, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00166	Silicone round drain 250 mm, FG 30, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00167	Silicone round drain 500 mm, FG 30, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00168	Silicone round drain 600 mm, FG 30, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00169	Silicone round drain 250 mm, FG 36, 5 lateral eyes, central opening, X-ray contrast	IIa



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A	VK00170	Silicone round drain 500 mm, FG 36, 5 lateral eyes, central opening, X-ray contrast	IIa
A	VK00174	Silicone-T-drain 500 mm, FG 12, web length 160 mm, X-ray contrast line	IIa
A	VK00176	Silicone-T-drain 500 mm, FG 15, web length 160 mm, X-ray contrast line	IIa
A	VK00178	Silicone-T-drain 500 mm, FG 18, web length 160 mm, X-ray contrast line	IIa
A	VK00180	Silicone-T-drain 500 mm, FG 20, web length 160 mm, X-ray contrast line	IIa
A	VK00182	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 10, cross-perforated 70 mm,	IIa
A	VK00183	Silicone-T-drain 500 mm, FG 24, web length 160 mm, X-ray contrast line	IIa
A	VK00185	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 12, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00187	Silicone drainage system two-part; secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 12, 5 lateral eyes; central opening, X-ray contrast line	IIa
A	VK00188	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 14, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00190	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 15, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00191	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 16, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00192	Silicone drainage system two-part; secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 15, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00194	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 18, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00197	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 21, 5 lateral eyes; central opening, X-ray contrast line	IIa
A	VK00198	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 20, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00201	Silicone-T-drain 700 mm, FG 12, web length 160 mm, cross-perforated, X-ray contrast line	IIa
A	VK00202	Silicone drainage system two-part; secretion bag 450 ml, bottom drain valve, NRV, silicone round drainage 1000 mm, FG 21, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00203	Silicone drainage system two-part; secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 20, 5 lateral eyes, central opening, X-ray contrast line	IIa

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A	VK00204	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 24, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00206	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 26, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00209	Silicone-T-drain 700 mm, FG 15, web length 160 mm, cross-perforated, X-ray contrast line	IIa
A	VK00210	Silicone drainage system two-part; secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 24, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00213	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 27, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00216	Silicone drainage system two-part; secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 27, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00217	Silicone drainage system closed (type Robinson); secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 30, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00220	Silicone drainage system two-part, secretion bag 450 ml, NRV, bottom drain valve; silicone round drainage 1000 mm, FG 30, 5 lateral eyes, central opening, X-ray contrast line	IIa
A	VK00222	Silicone-T-drain 500 mm, FG 24, web length 160 mm, cross-perforated, X-ray contrast line	IIa
A	VK00226	Yankauer big (FG 22)	IIa
A	VK00227	Yankauer medium (FG 18)	IIa
A	VK00228	Yankauer small (FG 12)	IIa
A	VK00269	ORIFLEX III 200 ml, 1080 mm, cut down connector, rubber/grommet; drain 500 mm, FG 10, cross-perforation 140 mm, X-ray contrast line; needle 195 mm	IIa
A	VK00270	ORIFLEX III 200 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 10, cross-perforation 140 mm, X-ray contrast line, needle 195 mm	IIa
A	VK00284	ORIFLEX II 450 ml, 1080 mm, cut down connector, rubber/grommet; drain 500 mm, FG 14, cross-perforation 140 mm, X-ray contrast line, needle 200 mm	IIa
A	VK00285	ORIFLEX II 450 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 14, cross-perforation 140 mm, X-ray contrast line, needle 200 mm	IIa
A	VK00290	ORIFLEX II 450 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 18, cross-perforation 140 mm, X-ray contrast line, needle 200 mm	IIa
A	VK00291	ORIFLEX II 450 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 8, cross-perforation 140 mm, X-ray contrast line, needle 200 mm	IIa
A	VK00316	ORIFLEX V 600 ml, 1080 mm, cut down connector, QL connection, chamber with non-return valve; drain 500 mm, FG 10, cross-perforation 140 mm, X-ray contrast line, needle 195 mm	IIa

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A	VK00317	ORIFLEX V 600 ml, 1080 mm, cut down connector, QL connection, chamber with non-return valve; drain 500 mm, FG 12 , cross-perforation 140 mm, X-ray contrast line, needle 200 mm	IIa
A	VK00319	ORIFLEX V 600 ml, 1080 mm, cut down connector, QL connection, chamber with non-return valve; drain 500 mm, FG 16 , cross-perforation 140 mm, X-ray contrast line, needle 200 mm	IIa
A	VK00322	ORIFLEX V 600 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 10, cross-perforation 140 mm, X-ray contrast line, needle 195 mm	IIa
A	VK00324	ORIFLEX V 600 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 12, cross-perforation 140 mm, X-ray contrast line, needle 200 mm	IIa
A	VK00326	ORIFLEX V 600 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 14, cross-perforation 140 mm, X-ray contrast line, needle 200 mm	IIa
A	VK00327	ORIFLEX V 600 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 16, cross-perforation 140 mm, X-ray contrast line, needle 200 mm	IIa
A	VK00339	ORIFLEX V 600 ml, 1080 mm, screw connector, QL connection	IIa
A	VK00373	ORIFLEX IV 400 ml, 1080 mm, screw connector, QL connection; drain 500 mm, FG 10, cross-perforation 140 mm, X-Ray contrast line; needle 195 mm; self-adhesive	IIa
A	VK00374	ORIFLEX IV 400 ml, 1080 mm, screw connector, QL connection; drain 500 mm, FG 12, cross-perforation 140 mm, X-Ray contrast line; needle 200 mm; self-adhesive	IIa
A	VK00413	ORIFLEX II 450 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 10 , cross-perforation 140 mm, X-ray contrast line; needle 195 mm	IIa
A	VK00420	ORIFLEX II 450 ml, 1080 mm, cut down connector, rubber/grommet; drain 500 mm, FG 10 , cross-perforation 140 mm, X-ray contrast line; needle 195 mm	IIa
A	VK00421	ORIFLEX II 450 ml, 1080 mm, cut down connector, rubber/grommet; drain 500 mm, FG 12, cross-perforation 140 mm, X-ray contrast line; needle 200 mm	IIa
A	VK00423	ORIFLEX II 450 ml, 1080 mm, cut down connector, rubber/grommet; drain 500 mm, FG 16, cross-perforation 140 mm, X-ray contrast line; needle 200 mm	IIa
A	VK00424	ORIFLEX II 450 ml, 1080 mm, cut down connector, rubber/grommet; drain 500 mm, FG 18, cross-perforation 140 mm, X-ray contrast line; needle 200 mm	IIa
A	VK00441	ORIFLEX II 450 ml, 1080 mm, screw conector, rubber/grommet; drain 500 mm, FG 16, cross-perforation 140 mm, X-Ray contrast line; needle 200 mm	IIa
A	VK00472	Mini Pack bellows 20 ml, cut down connector; drainage 500 mm, 6 FG, perforation 70 mm, X-ray contrast line; needle 60 mm	IIa
A	VK00473	Mini Pack bellows 20 ml, cut down connector, universal connector; drainage 500 mm, 6 FG, perforation 70 mm, X-ray contrast line; needle 60 mm	IIa
A	VK00474	Mini Pack bellows 20 ml, cut down connector; drainage 500 mm, 8 FG, cross-perforation 70 mm, X-ray contrast line; needle 60 mm	IIa
A	VK00475	Mini Pack bellows 20 ml, universal connector; drainage 500 mm, 8 FG, cross-perforation 70 mm, X-ray contrast line; needle 60 mm	IIa
A	VK00479	Mini Pack bellows 150 ml, cut down connector; drainage 500 mm, 6 FG, perforation 70 mm, X-ray contrast line; needle 60 mm	IIa
A	VK00480	Mini Pack bellows 150 ml, universal connector; drainage 500 mm, 6 FG, perforation 70 mm, X-ray contrast line; needle 60 mm	IIa
A	VK00481	Mini Pack bellows 150 ml, cut down connector; drainage 500 mm, 8 FG, cross-perforation 70 mm, X-ray contrast line; needle 60 mm	IIa



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A	VK00482	Mini Pack bellows 150 ml, universal connector; drainage 500 mm, 8 FG, cross-perforation 70 mm, X-ray contrast line; needle 60 mm	IIa
A	VK00492	Low Vacuum System bellow 350 ml, 1080 mm, cut down connector, non-return valve, QL connection; drain 500 mm, 14 FG, cross-perforation 70 mm, X-ray contrast line; needle 200 mm; secretion bag 450 ml, non-return valve, bottom drain valve	IIa
A	VK00495	Low Vacuum System bellow 350 ml, 1080 mm, cut down connector, non-return valve, QL connection; drain 500 mm, 8 FG, cross-perforation 70 mm, X-ray contrast line; needle 200 mm; secretion bag 450 ml, non-return valve, bottom drain valve	IIa
A	VK00503	Low Vacuum System bellow 350 ml, 1080 mm, cut down connector, non-return valve, QL connection; drain 500 mm, 10 FG, cross-perforation 60 mm, X-ray contrast line; needle 200 mm; secretion bag 450 ml, non-return valve, bottom drain valve	IIa
A	VK00504	Low Vacuum System bellow 350 ml, 1080 mm, cut down connector, non-return valve, QL connection; drain 500 mm, 14 FG, cross-perforation 60 mm, X-ray contrast line; needle 200 mm; secretion bag 450 ml, non-return valve, bottom drain valve	IIa
A	VK00506	Low Vacuum System bellow 350 ml, 1080 mm, screw connector, non-return valve, QL connection; drain 500 mm, 10 FG, cross-perforation 140 mm, X-ray contrast line; needle 200 mm; secretion bag 450 ml, non-return valve, bottom drain valve	IIa
A	VK00509	Secretion drainage set drain 800 mm, FG 12, cross-perforation 140 mm, X-ray contrast line; screw connector; secretion bag 450 ml, 1080 mm, non-return valve, bottom drain valve	IIa
A	VK00512	Quad Pack drainage 500 mm, 10 FG, cross-perforation 140 mm, X-Ray contrast line; tube 1080 mm, cut down connector, secretion stop	IIa
A	VK00534	Silicone round drain 600 mm, FG 30, 10 lateral eyes, central opening, bevel edge, X-ray contrast line, bevel edge	IIa
A	VK00535	Silicone round drain 500 mm, FG 36, 5 lateral eyes, central opening, bevel edge, X-ray contrast line	IIa
A	VK00539	ORIFLEX IV 400 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 10 cross-perforation 140 mm, X-Ray contrast line; needle 195 mm	IIa
A	VK00540	ORIFLEX IV 400 ml, 1080 mm, QL connection, cut down connector; chamber with non-return valve; drain 500 mm, FG 10, cross-perforation 140 mm, X-Ray contrast line; needle 195 mm	IIa
A	VK00545	ORIFLEX IV 400 ml, 1080 mm, QL connection, cut down connector, chamber with non-return valve; drain 500 mm, FG 16, cross-perforation 140 mm, X-Ray contrast line; needle 200 mm	IIa
A	VK00555	ORIFLEX IV 400 ml, 1080 mm, cut down connector, QL connection; drain 500 mm, FG 12, cross-perforation 140 mm, X-Ray contrast line; needle 200 mm	IIa
A	VK00556	ORIFLEX IV 400 ml, 1080 mm, cut down connector, QL; drain 500 mm, FG 14, cross-perforation 140 mm, X-Ray contrast line; needle 200 mm	IIa
A	VK00571	Biliary drain 1000 mm, FG 9, middle cross-perforated 70 mm (Neuhaus)	IIa
A	VK00572	Biliary drain 1000 mm, FG 12, middle five lateral eyes (Neuhaus)	IIa
A	VK00573	Biliary drain 1000 mm, FG 21, middle five lateral eyes (Neuhaus)	IIa
A	VK00583	Silicone round drain 500 mm, FG 36, 1 lateral eye, central opening, X-Ray contrast	IIa
A	VK01075	Biliary drain 650 mm, FG 9, middle cross-perforated 70 mm (Neuhaus)	IIa
A	VK01076	Biliary drain 650 mm, FG 7, middle cross-perforated 70 mm (Neuhaus)	IIa



## Annex

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Class IIa

A	VK01077	Biliary drain 650 mm, FG 6, middle perforated 70 mm (Neuhaus)	IIa
A	VK01101	Silicone round drain 700 mm, FG 36, 15 lateral eyes, central opening, bevel edge, X-Ray contrast line	IIa



# EC-Declaration of Conformity

ORIPLAST GmbH  
Hermannstraße 150 Industriegebiet  
66538 Neunkirchen  
Deutschland

Declare on sole responsibility that the following products

## Wound-Secretion-Management

- Class Is -

meet all provisions of Directive 93/42/EEG Annex V and is eligible to carry the mark



The individual products with their article numbers are listed in the appendix.

Notified Body:

DQS Medizinprodukte GmbH  
August-Schanz-Straße 21  
D - 60433 Frankfurt am Main

Expiry date: bis 09.01.2024

Neunkirchen, den 12.02.2021  
Ort, Datum

A handwritten signature in blue ink, reading 'A. Sauerwein'.

General Manager: Alexander Sauerwein

# Annex

## Declaration of Conformity

DMF A  
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Management)  
Class Is

DMF	REF	Article	Risk
			Class
A	VK00001	Suction connecting tube 1800 mm, FG 33, one sided silicone connector, one sided finger tip (big)	Is
A	VK00005	Suction connecting tube 1800 mm, FG 18, one sided silicone connector 5 x 1,5 mm, one sided silicone connector 7 x 1,5 mm	Is
A	VK00006	Suction connecting tube 1800 mm, FG 18, one sided silicone connector, one sided LL male	Is
A	VK00007	Suction connecting tube 1000 mm, FG 27, both sided silicone connector	Is
A	VK00010	Silicone reservoir 100 ml, graduated	Is
A	VK00035	Distribution line adapter QL female, grommet	Is
A	VK00053	THORAFLEX I screw attachment for one bottle; patient tube with step connector, vacuum tube, marked rising tube (type Bulau)	Is
A	VK00054	THORAFLEX III screw attachment for one bottle; patient tube with step connector, vacuum tube, marked rising pipe, fixed above tube exit	Is
A	VK00055	THORAFLEX VI screw attachment for one bottle; patient tube (silicone), FG 36, step connector, vacuum tube, marked rising tube, tube reinforcement	Is
A	VK00056	THORAFLEX secretion collection system; screw attachment for one bottle; patient tube with step connector, vacuum tube, dripping pipe shortened and fixed	Is
A	VK00061	THORAFLEX VIII screw attachment for two bottles; patient tube with step connector, vacuum tube, marked rising tube, fixed dripping tube, connection tube	Is
A	VK00062	THORAFLEX screw attachment for two bottles; 2x patient tube with step connector, vacuum tube, fixed dripping tubes, 2x connecting tube	Is
A	VK00063	THORAFLEX XIV screw attachment for two bottles; patient tube with step connector, vacuum tube, HEIMLICH valve, fixed dripping tube, rising tube, suction control	Is
A	VK00064	THORAFLEX XXXII screw attachment with 2 bottles; 1000 ml, patient tube with step connector, vacuum tube, rising tube with control mark	Is
A	VK00066	THORAFLEX XXXVIII screw attachment for 2 bottles; patient tube with step connector, vacuum tube, connection tube, fixed dripping tube, rising tube, suction	Is
A	VK00075	THORAFLEX XXXII screw attachment with 3 bottles; 1000 ml, patient tube with step connector, vacuum tube	Is
A	VK00095	VENOFLEX 450 ml, 1080 mm, LL male, protection cap	Is
A	VK00096	ORIFLEX II replacement bottle 450 ml	Is
A	VK00097	ORIFLEX III replacement bottle 200 ml	Is
A	VK00102	Low Vacuum System bellow 350 ml, 1080 mm, non-return valve, QL connection; secretion bag 450 ml, non-return valve, bottom drain valve, Luer slip	Is
A	VK00104	Low Vacuum System bellow 350 ml, 1080 mm, non-return valve, QL connection; secretion bag 450 ml, non-return valve, bottom drain valve, Luer-Rekord slip	Is
A	VK00105	Low Vacuum System bellow 350 ml, 1080 mm, non-return valve, QL connection; without secretion bag	Is
A	VK00109	THORAFLEX bottle 1000 ml	Is
A	VK00111	Suction connecting tube 1900 mm, FG 40, one sided step connector	Is
A	VK00112	Suction connecting tube 2100 mm, FG 25, both sided funnel connector	Is
A	VK00113	Suction connecting tube 3000 mm, FG 25, both sided funnel connector	Is



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Class Is

A	VK00115	Suction connecting tube 3000 mm, FG 25, soft	Is
A	VK00119	Suction connecting tube 3000 mm, FG 25, one sided funnel connector	Is
A	VK00120	Suction connecting tube 3500 mm, FG 25, one sided funnel connector, one sided Sherwood connector	Is
A	VK00126	Suction connecting tube 1900 mm, FG 27, both sided silicone connector	Is
A	VK00127	Suction connecting tube 1300 mm, FG 27, both sided silicone connector	Is
A	VK00128	Suction connecting tube 1600 mm, FG 25, both sided silicone connector	Is
A	VK00129	Suction connecting tube 1500 mm, FG 25, both sided Sherwood connector, slide	Is
A	VK00130	Suction connecting tube 3000 mm, FG 27, one sided finger tip, one sided silicone	Is
A	VK00131	Suction connecting tube 1600 mm, FG 25, one sided finger tip, one sided silicone	Is
A	VK00135	Pleura puncture set 1500 ml, NRV, 900 mm, three-way stopcock blue, LL male; syringe 50 ml; without needle	Is
A	VK00230	HEIMLICH valve both sided step connector, LL male, HEIMLICH valve	Is
A	VK00231	Screw cap white, for Quick-Lock female	Is
A	VK00253	Distribution line 3-way screw connectors, LL female, step connector	Is
A	VK00254	Distribution line 4-way screw connectors, LL female, step connector	Is
A	VK00257	Distribution line 2-way screw connectors, 1650 mm with extension 200 mm, LL female, LL male, Sherwood connector	Is
A	VK00258	Distribution line 3-way screw connectors, 1650 mm with extension 200 mm, LL female, LL male, Sherwood connector with cap	Is
A	VK00259	Distribution line 3-way screw connectors, 1650 mm with extension 200 mm, LL female, QL connection, Sherwood connector with cap	Is
A	VK00261	Distribution line 3-way screw connectors, 1000 mm with extension 2000 mm, LL female, LL male, Sherwood connector with cap	Is
A	VK00262	Distribution line 3-way screw connectors, 1000 mm with extension 2000 mm, LL female, QL connection, Sherwood connector with cap	Is
A	VK00263	Distribution line 3-way screw connectors, 1650 mm with extension 70 mm, LL female, QL connection, Sherwood connector with cap	Is
A	VK00295	THORAFLEX Drainage System; screw attachment with one bottle, 1000 ml, patient tube with step connector, vacuum tube, HEIMLICH valve, marked rising tube	Is
A	VK00296	THORAFLEX XXXIV screw attachment with 2 bottles; 1000 ml, patient tube with step connector, vacuum tube, fixed dripping tube, marked rising tube	Is
A	VK00297	THORAFLEX XXXIX screw attachment with 2 bottles; 1000 ml, patient tube with step connector, vacuum tube, fixed dripping tube, suction control NRV	Is
A	VK00298	THORAFLEX XXXVIII screw attachment with 2 bottles; 1000 ml, patient tube with step connector, vacuum tube, suction control, NRV, tube reinforcement (blue)	Is
A	VK00308	ORIFLEX V replacement bottle 600 ml, QL	Is
A	VK00309	ORIFLEX V replacement bottle 600 ml, QL, cap	Is
A	VK00312	ORIFLEX V replacement bottle 600 ml, QL, self-adhesive stripe	Is
A	VK00314	ORIFLEX V 600 ml, 1080 mm, cut down connector, rubber/grommet	Is
A	VK00315	ORIFLEX V 600 ml, 1080 mm, cut down connector, QL connection	Is
A	VK00348	ORIFLEX IV replacement bottle 400 ml, QL	Is
A	VK00349	ORIFLEX IV replacement bottle 400 ml, QL, cap, self-adhesive stripe	Is
A	VK00351	ORIFLEX IV 400 ml, 1080 mm, cut down connector	Is
A	VK00352	ORIFLEX IV 400 ml, 1080 mm, cut down connector, QL connection	Is



# Annex

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Class Is

A	VK00359	ORIFLEX IV 400 ml, 1080 mm, cut down connector, one slide clamp	Is
A	VK00368	ORIFLEX IV 400 ml, 1080 mm, cut down connector, QL connection, self-adhesive	Is
A	VK00372	ORIFLEX IV 400 ml, 1080 mm, screw connector, QL connection; self-adhesive stripe	Is
A	VK00378	Redon connecting tube - universal 1080 mm, cut down connector, for FG 6-18	Is
A	VK00383	Redon connecting tube - universal 1080 mm, cut down connector, rubber/grommet, for FG 6-18	Is
A	VK00384	Redon connecting tube - universal 1080 mm, cut down connector, slide clamp, QL, for FG 6-18	Is
A	VK00389	ORTHOFLEX II surgery drainage system (gravity) 450 ml, 1080 mm, screw connector, QL, LL female, filter 0.2 µm	Is
A	VK00390	ORIFLEX I 450 ml (50 % vacuum), 1080 mm, cut down connector, secretion stop	Is
A	VK00393	ORIFLEX I 450 ml, 1080 mm, screw connector, QL connection	Is
A	VK00394	ORIFLEX I 450 ml (50 % vacuum), 1080 mm, screw connector, QL connection	Is
A	VK00395	ORIFLEX I 450 ml (50 % vacuum) , 1080 mm, cut down connector, QL connection	Is
A	VK00396	ORTHOFLEX II replacement bottle (gravity) 450 ml, QL, LL female, filter 0.2 µm	Is
A	VK00398	ORIFLEX I replacement bottle 450 ml (50 % vacuum), LL male	Is
A	VK00399	ORIFLEX I replacement bottle 450 ml, QL	Is
A	VK00400	ORIFLEX I replacement bottle 450 ml (50% vacuum) , QL	Is
A	VK00405	ORIFLEX II replacement bottle 450 ml, QL, cap	Is
A	VK00409	ORIFLEX II replacement bottle 450 ml, QL	Is
A	VK00411	ORIFLEX II 450 ml, 1080 mm, cut down connector, secretion stop	Is
A	VK00412	ORIFLEX II 450 ml, 1080 mm, cut down connector, QL connection	Is
A	VK00426	ORIFLEX II 450 ml, 1080 mm, cut down connector, rubber/grommet, PVC free	Is
A	VK00428	ORIFLEX II 450 ml, 1080 mm, cut down connector, not disconnectable	Is
A	VK00429	ORIFLEX II 450 ml, 1080 mm, screw connector, rubber/grommet	Is
A	VK00431	ORIFLEX II 450 ml, 1080 mm, screw connector, QL connection	Is
A	VK00444	ORIFLEX II 450 ml, 1080 mm, screw connector, not disconnectable	Is
A	VK00454	ORIFLEX III 200 ml, 1080 mm, cut down connector, rubber/grommet	Is
A	VK00462	ORIFLEX III 200 ml, 1080 mm, cut down connector, not disconnectable	Is
A	VK00463	ORIFLEX III 200 ml, 1080 mm, screw connector, rubber/grommet	Is
A	VK00464	ORIFLEX III 200 ml, 1080 mm, screw connector, not disconnectable	Is
A	VK00465	ORIFLEX III 200 ml, 1080 mm, cut down connector, QL connection	Is
A	VK00466	ORIFLEX III 200 ml, 1080 mm, screw connector, QL connection	Is
A	VK00468	ORIFLEX III replacement bottle 200 ml (50% vacuum), QL	Is
A	VK00469	ORIFLEX III replacement bottle 200 ml, QL, cap	Is
A	VK00470	ORIFLEX III replacement bottle 200 ml, QL	Is
A	VK00476	Replacement bellows for Mini Pack 20 ml, cut down connector	Is
A	VK00483	Replacement bellows for Mini Pack 150 ml, cut down connector	Is
A	VK00484	Replacement bellows for Mini Pack 150 ml, universal connector	Is
A	VK00487	Low Vacuum System bellow 350 ml, 1080 mm, cut down connector, non-return valve, QL connection; secretion bag 450 ml, non-return valve, bottom drain valve	Is
A	VK00497	Low Vacuum System bellow 350 ml, 1080 mm, screw connector, non-return valve, QL connection; secretion bag 450 ml, non-return valve, bottom drain valve	Is
A	VK00505	Low Vacuum System bellow 350 ml, 1080 mm, srew connector, non-return valve, QL connection; without secretion bag	Is

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DMF A  
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Class Is

A	VK00515	Tube adapter 150 mm, 25 FG, both sided Sherwood connector	Is
A	VK00516	Suction connecting tube 2000 mm, FG 25, both sided Sherwood connector	Is
A	VK00518	Suction connecting tube 2400 mm, FG 25, both sided Sherwood connector	Is
A	VK00519	Suction connecting tube 3000 mm, FG 25 , both sided Sherwood connector	Is
A	VK00523	Suction connecting tube 3000 mm, FG 25, both sided Sherwood connector, soft	Is
A	VK00524	Suction connecting tube 3000 mm, FG 25, one sided Sherwood connector, one sided silicone connector	Is
A	VK00527	Suction connecting tube 1600 mm, FG 25, one sided Sherwood connector	Is
A	VK00529	Suction connecting tube 1600 mm, FG 25, one sided Sherwood connector, one sided finger tip	Is
A	VK00547	ORIFLEX III replacement bottle 200 ml, QL, vacuum indicator without scale division	Is
A	VK00548	ORIFLEX III 200 ml, 1080 mm, cut down connector, QL connection, vacuum indicator	Is
A	VK00549	ORIFLEX III 200 ml, 1080 mm, screw connector, QL connection, vacuum indicator	Is
A	VK00557	ORIFLEX IV 400 ml, 1080 mm, screw connector, QL connection	Is
A	VK00580	Tube adapter 75 mm, FG, 42 one sided step connector	Is
A	VK00582	Thorax drainage connector triple, 1600 mm, SH, step connectors, LL male, roberts	Is
A	VK00886	Y-connector 2x à 200 mm, 2x step connector; for thoracic drainage	Is
A	VK00892	Biliary drainage system 450 ml, NRV, bottom drain valve, pipette connector	Is
A	VK00916	Suction tube 280 mm, Y-connector	Is
A	VK00950	Fingertip with round surface	Is
A	VK00951	Fingertip with LL male	Is
A	VK00952	Fingertip with Luer slip	Is
A	VK01060	Suction tube 2200 mm, FG 25	Is

# ORIPLAST

## CE - Deklaracja Zgodności

ORIPLAST GmbH  
HermannstraBe 150 Industriegebiet  
66538 Neunkirchen  
Deutschland

Deklaruje na wyłączną odpowiedzialność, że następujące produkty

### Wound-Secretion-Management

- Klasa II -

spełnia wszystkie przepisy załącznika II do dyrektywy 93/42/EWG i kwalifikuje się do oznaczania znakiem jakości

CE<sub>0297</sub>

Poszczególne produkty wraz z numerami artykułów są wymienione w załączniku

Jednostka notyfikowana

DQS Medizinprodukte GmbH  
August-Schanz-StraBe 21  
D - 60433 Frankfurt am Main

Data ważności: bis 09.01.2024

Neunkirchen, den 12.02.2021  
Ort, Datum

General Manager: Alexander Sauerwein

DMF	REF	Article	Risk
			Class
A	VK00011	Silikonowy płaski dren długość 1000 mm, szerokość 7 mm, wysokość 4 mm, perforacja 3/4	IIa
A	VK00012	Silikonowy płaski dren długość 1000 mm, szerokość 10 mm, wysokość 4 mm, perforacja 3/4	IIa
A	VK00013	Silikonowy płaski dren długość 1000 mm, szerokość 7 mm, wysokość 4 mm, pełna perforacja	IIa
A	VK00014	Silikonowy płaski dren długość 1000 mm, szerokość 10 mm, wysokość 4mm, pełna perforacja	IIa
A	VK00017	Silikonowy okrągły dren 1300 mm, FG 15, 230 mm perforowany krzyżowo, złącze Luer, linia kontrastu RTG	IIa
A	VK00021	Zestaw ssący z płaskim drenem, objętość zbiornika 1000 mm <sup>3</sup> ; płaski dren: szerokość 10 mm, wysokość 4 mm, perforacja 3/4	IIa
A	VK00022	Zestaw ssący z płaskim drenem, objętość zbiornika 1000 mm <sup>3</sup> ; płaski dren: szerokość: 7 mm, wysokość 4 mm, pełna perforacja	IIa
A	VK00023	Zestaw ssący z płaskim drenem, objętość zbiornika 1000 mm <sup>3</sup> ; płaski dren: szerokość 10 mm, wysokość 4 mm, pełna perforacja	IIa
A	VK00024	Silikonowy dren kapilarny długość 300 mm, szerokość 6 mm, linia kontrastu RTG (Penrose)	IIa
A	VK00025	Silikonowy dren kapilarny długość 300 mm, szerokość 8 mm, linia kontrastu RTG (Penrose)	IIa
A	VK00026	Silikonowy dren kapilarny długość 300 mm, szerokość 10 mm, linia kontrastu RTG (Penrose)	IIa
A	VK00027	Silikonowy dren kapilarny długość 100 mm, szerokość 10 mm, linia kontrastu RTG (Penrose)	IIa
A	VK00028	Silikonowy dren kapilarny długość 300 mm, szerokość 12 mm, linia kontrastu RTG (Penrose)	IIa
A	VK00036	Dren Redon 800 mm, FG 8, 140 mm perforacja środkowa, linia kontrastu RTG	IIa
A	VK00045	Dren Redon 800 mm, FG 10, 140 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00046	Dren Redon 800 mm, FG 12, 140 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00051	Dren Redon 800 mm, FG 10, 140 mm perforowany krzyżowo, linia kontrastu RTG; trokar	IIa
A	VK00052	Dren Redon 800 mm, FG 12, 140 mm perforowany krzyżowo, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00058	Dren Redon 500 mm, FG 6, 70 mm perforacja, linia kontrastu RTG	IIa
A	VK00059	Dren Redon 500 mm, FG 6, 140 mm perforacja, linia kontrastu RTG	IIa
A	VK00067	Dren Redon 500 mm, FG 8, 70 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00068	Dren Redon 500 mm, FG 8, 140 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00069	Dren Redon 500 mm, FG 8, 140 mm perforowany krzyżowo, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00072	Dren Redon 500 mm, FG 10, 70 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00073	Dren Redon 500 mm, FG 10, 140 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00074	Dren Redon 500 mm, FG 10, 140 mm perforowany krzyżowo, linia kontrastu RTG; trokar 195 mm	IIa
A	VK00076	Dren Redon 500 mm, FG 12, 70 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00077	Dren Redon 500 mm, FG 12, 140 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00078	Dren Redon 500 mm, FG 12, 140 mm perforowany krzyżowo, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00079	Dren Redon 500 mm, FG 14, 70 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00080	Dren Redon 500 mm, FG 14, 140 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00081	Dren Redon 500 mm, FG 14, 140 mm perforowany krzyżowo, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00082	Dren Redon 500 mm, FG 16, 70 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00083	Dren Redon 500 mm, FG 16, 140 mm perforowany krzyżowo, linia kontrastu RTG	IIa

A	VK00084	Dren Redon 500 mm, FG 16, 140 mm perforowany krzyżowo, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00085	Dren Redon 700 mm, FG 8, 70 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00086	Dren Redon 500 mm, FG 18, 70 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00087	Dren Redon 500 mm, FG 18, 140 mm perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00088	Dren Redon 500 mm, FG 18, 140 mm perforowany krzyżowo, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00090	ORIFLEX IV butelka wymienna 400 ml	IIa
A	VK00098	Dren Redon 500 mm, FG 6, perforacja 70 mm, linia kontrastu RTG; trokar 60 mm	IIa
A	VK00099	Dren Redon 500 mm FG 8, 70 mm perforowany krzyżowo, linia kontrastu RTG; trokar 60	IIa
A	VK00100	Mini Pack mieszek 150 ml, łącznik z docinaniem, Luer-Rekord-Steck; dren silikonowy 500 mm, 10 FG, perforowany krzyżowo 140 mm, linia kontrastu RTG	IIa
A	VK00103	System niskociśnieniowy mieszek 350 ml, 1080 mm, łącznik z docinaniem, zastawka antyzwrotna, połączenie QL; dren 500 mm, 10 FG, perforowany krzyżowo 140 mm, RTG	IIa
A	VK00134	Zestaw do punkcji opłucnej 1500 ml, NRV, 900 mm, trójdrożny zawór odcinający niebieski, strzykawka 50 ml, igła iniekcyjna 14 G	IIa
A	VK00136	Zestaw do punkcji opłucnej 2000 ml, NRV, dolny zawór spustowy, 900 mm, trójdrożny zawór odcinający niebieski, LL męski, strzykawka 50 ml; igła iniekcyjna 14 G	IIa
A	VK00140	Zestaw do punkcji opłucnej 1500 ml, NRV, 900 mm, trójdrożny zawór odcinający niebieski odłączalny, LL męski, strzykawka 50 ml; igła iniekcyjna 14 G	IIa
A	VK00144	Silikonowy okrągły dren 500 mm, FG 16, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00145	Silikonowy okrągły dren 500 mm, FG 15, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00146	Silikonowy okrągły dren 800 mm, FG 15, 240 mm perforacja krzyżowa, kontrast RTG	IIa
A	VK00148	Silikonowy okrągły dren 250 mm, FG 12, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00149	Silikonowy okrągły dren 500 mm, FG 12, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00150	Silikonowy okrągły dren 500 mm, FG 24, 2 otwory boczne, 1 centralny, kontrast RTG	IIa
A	VK00152	Silikonowy okrągły dren 500 mm, FG 10, 70 mm perforacja krzyżowa, central opening, kontrast RTG	IIa
A	VK00153	Silikonowy okrągły dren 500 mm, FG 10, 140 mm perforacja krzyżowa, otwór centralny, kontrast RTG	IIa
A	VK00155	Silikonowy okrągły dren 500 mm, FG 8, 70 mm perforacja krzyżowa, otwór centralny, kontrast RTG	IIa
A	VK00156	Silikonowy okrągły dren 250 mm, FG 18, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00157	Silikonowy okrągły dren 500 mm, FG 18, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00158	Silikonowy okrągły dren 250 mm, FG 21, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00159	Silikonowy okrągły dren 500 mm, FG 21, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00160	Silikonowy okrągły dren 250 mm, FG 24, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00161	Silikonowy okrągły dren 500 mm, FG 24, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00162	Silikonowy okrągły dren 500 mm, FG 25, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00164	Silikonowy okrągły dren 500 mm, FG 27, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00165	Silikonowy okrągły dren 600 mm, FG 27, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00166	Silikonowy okrągły dren 250 mm, FG 30, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00167	Silikonowy okrągły dren 500 mm, FG 30, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00168	Silikonowy okrągły dren 600 mm, FG 30, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00169	Silikonowy okrągły dren 250 mm, FG 36, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa



A	VK00170	Silikonowy okrągły dren 500 mm, FG 36, 5 otworów bocznych, 1 centralny, kontrast RTG	IIa
A	VK00174	Silikonowy dren T 500 mm, FG 12, długość T 160 mm, linia kontrastu RTG	IIa
A	VK00176	Silikonowy dren T 500 mm, FG 15, długość T 160 mm, linia kontrastu RTG	IIa
A	VK00178	Silikonowy dren T 500 mm, FG 18, długość T 160 mm, linia kontrastu RTG	IIa
A	VK00180	Silikonowy dren T 500 mm, FG 20, długość T 160 mm, linia kontrastu RTG	IIa
A	VK00182	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 10, perforowany krzyżowo 70 mm,	IIa
A	VK00183	Silikonowy dren T 500 mm, FG 24, długość T 160 mm, linia kontrastu RTG	IIa
A	VK00185	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 12, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00187	Dwuczęściowy silikonowy system drenażu; worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 12, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00188	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 14, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00190	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, dolny zawór; silikonowy okrągły dren 1000 mm, FG 15, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00191	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 16, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00192	Dwuczęściowy silikonowy system drenażu; worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 15, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00194	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 18, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00197	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 21, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00198	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 20, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00201	Silikonowy dren T 700 mm, FG 12, długość T 160 mm, perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00202	Dwuczęściowy silikonowy system drenażu; worek 450 ml, dolny zawór, NRV, silikonowy okrągły dren 1000 mm, FG 21, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00203	Dwuczęściowy silikonowy system drenażu; worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 20, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa

A	VK00204	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 24, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00206	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 26, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00209	Silikonowy dren T 700 mm, FG 15, długość T 160 mm, perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00210	Dwuczęściowy silikonowy system drenażu; worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 24, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00213	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 27, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00216	Dwuczęściowy silikonowy system drenażu; worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 27, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00217	Zamknięty silikonowy system drenażu (typ Robinson); worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 30, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00220	Dwuczęściowy silikonowy system drenażu; worek 450 ml, NRV, dolny zawór; silikonowy okrągły dren 1000 mm, FG 30, 5 otworów bocznych, 1 centralny, linia kontrastu RTG	IIa
A	VK00222	Silikonowy dren T 500 mm, FG 24, długość 160 mm, perforowany krzyżowo, linia kontrastu RTG	IIa
A	VK00226	Yankauer duży (FG 22)	IIa
A	VK00227	Yankauer średni (FG 18)	IIa
A	VK00228	Yankauer mały (FG 12)	IIa
A	VK00269	ORIFLEX III 200 ml, 1080 mm, łącznik z docinaniem, gumowy/przepust; dren 500 mm, FG 10, perforowany krzyżowo 140 mm, linia kontrastu RTG; trokar 195 mm	IIa
A	VK00270	ORIFLEX III 200 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 10, perforowany krzyżowo 140 mm, linia kontrastu RTG ; trokar 195 mm	IIa
A	VK00284	ORIFLEX II 450 ml, 1080 mm, łącznik z docinaniem, gumowy/przepust; dren 500 mm, FG 14, perforowany krzyżowo 140 mm, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00285	ORIFLEX II 450 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 14, perforowany krzyżowo 140 mm, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00290	ORIFLEX II 450 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 18, perforowany krzyżowo 140 mm, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00291	ORIFLEX II 450 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 8, perforowany krzyżowo 140 mm, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00316	ORIFLEX V 600 ml, 1080 mm, łącznik z docinaniem, łącznik QL, komora z zastawką antyzwrotną; dren 500 mm, FG 10, perforowany krzyżowo 140 mm, linia kontrastu RTG ; trokar 195 mm	IIa

A	VK00317	ORIFLEX V 600 ml, 1080 mm, łącznik z docinaniem, łącznik QL, komora z zastawką antyzwrotną; dren 500 mm, FG 12, perforowany krzyżowo 140 mm, linia kontrastu RTG, trokar 200 mm	IIa
A	VK00319	ORIFLEX V 600 ml, 1080 mm, łącznik z docinaniem, łącznik QL, komora z zastawką antyzwrotną; dren 500 mm, FG 16, perforowany krzyżowo 140 mm, linia kontrastu RTG, trokar 200 mm	IIa
A	VK00322	ORIFLEX V 600 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 10, perforowany krzyżowo 140 mm, linia kontrastu RTG, trokar 195 mm	IIa
A	VK00324	ORIFLEX V 600 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 12, perforowany krzyżowo 140 mm, linia kontrastu RTG, trokar 200 mm	IIa
A	VK00326	ORIFLEX V 600 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 14, perforowany krzyżowo 140 mm, linia kontrastu RTG, trokar 200 mm	IIa
A	VK00327	ORIFLEX V 600 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 16, perforowany krzyżowo 140 mm, linia kontrastu RTG, trokar 200 mm	IIa
A	VK00339	ORIFLEX V 600 ml, 1080 mm, łącznik wkręcany, łącznik QL	IIa
A	VK00373	ORIFLEX IV 400 ml, 1080 mm, łącznik wkręcany, łącznik QL; dren 500 mm, FG 10, perforowany krzyżowo 140 mm, linia kontrastu RTG, trokar 195 mm; samoprzylepny	IIa
A	VK00374	ORIFLEX IV 400 ml, 1080 mm, łącznik wkręcany, łącznik QL; dren 500 mm, FG 12, perforowany krzyżowo 140 mm, linia kontrastu RTG, trokar 200 mm; samoprzylepny	IIa
A	VK00413	ORIFLEX II 450 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 10, perforacja krzyżowa 140 mm, linia kontrastu RTG, trokar 195 mm	IIa
A	VK00420	ORIFLEX II 450 ml, 1080 mm, łącznik z docinaniem, gumowy/przepust; dren 500 mm, FG 10, perforacja krzyżowa 140 mm, linia kontrastu RTG, trokar 195 mm	IIa
A	VK00421	ORIFLEX II 450 ml, 1080 mm, łącznik z docinaniem, gumowy/przepust; dren 500 mm, FG 12, perforacja krzyżowa 140 mm, linia kontrastu RTG, trokar 200 mm	IIa
A	VK00423	ORIFLEX II 450 ml, 1080 mm, łącznik z docinaniem, gumowy/przepust; dren 500 mm, FG 16, perforacja krzyżowa 140 mm, linia kontrastu RTG, trokar 200 mm	IIa
A	VK00424	ORIFLEX II 450 ml, 1080 mm, łącznik z docinaniem, gumowy/przepust; dren 500 mm, FG 18, perforacja krzyżowa 140 mm, linia kontrastu RTG, trokar 200 mm	IIa
A	VK00441	ORIFLEX II 450 ml, 1080 mm, łącznik wkręcany, gumowy/przepust; dren 500 mm, FG 16, perforacja krzyżowa 140 mm, linia kontrastu RTG, trokar 200 mm	IIa
A	VK00472	Mini Pack mieszek 20 ml, łącznik z docinaniem; drenaż 500 mm, 6 FG, perforacja krzyżowa 70 mm, linia kontrastu RTG, trokar 60 mm	IIa
A	VK00473	Mini Pack mieszek 20 ml, łącznik z docinaniem, łącznik uniwersalny; drenaż 500 mm, 6 FG, perforacja krzyżowa 70 mm, linia kontrastu RTG, trokar 60 mm	IIa
A	VK00474	Mini Pack mieszek 20 ml, łącznik z docinaniem; drenaż 500 mm, 8 FG, perforacja krzyżowa 70 mm, linia kontrastu RTG, trokar 60 mm	IIa
A	VK00475	Mini Pack mieszek 20 ml, uniwersalny łącznik; drenaż 500 mm, 8 FG, perforacja krzyżowa 70 mm, linia kontrastu RTG, trokar 60 mm	IIa
A	VK00479	Mini Pack mieszek 150 ml, łącznik z docinaniem; drenaż 500 mm, 6 FG, perforacja krzyżowa 70 mm, linia kontrastu RTG, trokar 60 mm	IIa
A	VK00480	Mini Pack mieszek 150 ml, uniwersalny łącznik; drenaż 500 mm, 6 FG, perforacja krzyżowa 70 mm, linia kontrastu RTG, trokar 60 mm	IIa
A	VK00481	Mini Pack mieszek 150 ml, łącznik z docinaniem; drenaż 500 mm, 8 FG, perforacja krzyżowa 70 mm, linia kontrastu RTG, trokar 60 mm	IIa

A	VK00482	Mini Pack mieszek 150 ml, uniwersalny łącznik; drenaż 500 mm, 8 FG, perforacja krzyżowa 70 mm, linia kontrastu RTG, trokar 60 mm	IIa
A	VK00492	System niskociśnieniowy mieszek 350 ml, 1080 mm, łącznik z docinaniem, zastawka antyzwrotna, łącznik QL; dren 500 mm, 14 FG, perforacja krzyżowa 70 mm, linia kontrastu RTG; trokar 200 mm; worek 450 ml, zastawka antyzwrotna, kranik	IIa
A	VK00495	System niskociśnieniowy mieszek 350 ml, 1080 mm, łącznik z docinaniem, zastawka antyzwrotna, łącznik QL; dren 500 mm, 8 FG, perforacja krzyżowa 70 mm, linia kontrastu RTG; trokar 200 mm; worek 450 ml, zastawka antyzwrotna, kranik	IIa
A	VK00503	System niskociśnieniowy mieszek 350 ml, 1080 mm, łącznik z docinaniem, zastawka antyzwrotna, łącznik QL; dren 500 mm, 10 FG, perforacja krzyżowa 60 mm, linia kontrastu RTG; trokar 200 mm; worek 450 ml, zastawka antyzwrotna, kranik	IIa
A	VK00504	System niskociśnieniowy mieszek 350 ml, 1080 mm, łącznik z docinaniem, zastawka antyzwrotna, łącznik QL; dren 500 mm, 14 FG, perforacja krzyżowa 60 mm, linia kontrastu RTG; trokar 200 mm; worek 450 ml, zastawka antyzwrotna, kranik	IIa
A	VK00506	System niskociśnieniowy mieszek 350 ml, 1080 mm, łącznik wkręcany, zastawka antyzwrotna, łącznik QL; dren 500 mm, 10 FG, perforacja krzyżowa 140 mm, linia kontrastu RTG; trokar 200 mm; worek 450 ml, zastawka antyzwrotna, kranik	IIa
A	VK00509	Zestaw do drenażu wydzieliny 800 mm, FG 12, perforacja krzyżowa 140 mm, linia kontrastu RTG; łącznik wkręcany; worek 450 ml, 1080 mm, zastawka antyzwrotna, kranik	IIa
A	VK00512	Drenaż Quad Pack 500 mm, 10 FG, perforacja krzyżowa 140 mm, linia kontrastu RTG; dren 1080 mm, łącznik z docinaniem, zatrzymanie wydzielania	IIa
A	VK00534	Silikonowy okrągły dren 600 mm, FG 30, 10 otworów bocznych, 1 centralny, skośna krawędź, linia kontrastu RTG	IIa
A	VK00535	Silikonowy okrągły dren 500 mm, FG 36, 5 otworów bocznych, 1 centralny, skośna krawędź, linia kontrastu RTG	IIa
A	VK00539	ORIFLEX IV 400 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 10 perforacja krzyżowa 140 mm, linia kontrastu RTG; trokar 195 mm	IIa
A	VK00540	ORIFLEX IV 400 ml, 1080 mm, łącznik QL, łącznik z docinaniem; komora z zastawką antyzwrotną; dren 500 mm, FG 10, perforacja krzyżowa 140 mm, linia kontrastu RTG; trokar 195 mm	IIa
A	VK00545	ORIFLEX IV 400 ml, 1080 mm, łącznik QL, łącznik z docinaniem, komora z zastawką antyzwrotną; dren 500 mm, FG 16, perforacja krzyżowa 140 mm, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00555	ORIFLEX IV 400 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 12, perforacja krzyżowa 140 mm, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00556	ORIFLEX IV 400 ml, 1080 mm, łącznik z docinaniem, łącznik QL; dren 500 mm, FG 14, perforacja krzyżowa 140 mm, linia kontrastu RTG; trokar 200 mm	IIa
A	VK00571	Dren żółciowy 1000 mm, FG 9, środkowo perforowany krzyżowo 70 mm (Neuhaus)	IIa
A	VK00572	Dren żółciowy 1000 mm, FG 12, środkowo 5 otworów bocznych (Neuhaus)	IIa
A	VK00573	Dren żółciowy 1000 mm, FG 21, środkowo 5 otworów bocznych (Neuhaus)	IIa
A	VK00583	Silikonowy okrągły dren 500 mm, FG 36, 5 otworów bocznych, 1 centralny, RTG	IIa
A	VK01075	Dren żółciowy 650 mm, FG 9, środkowo perforowany krzyżowo 70 mm (Neuhaus)	IIa
A	VK01076	Dren żółciowy 650 mm, FG 7, środkowo perforowany krzyżowo 70 mm (Neuhaus)	IIa

ORIPLAST

## Aneks

### Deklaracja Zgodności

DMF A  
(Wound-Secretion-  
Management)  
Klasa IIa

A	VK01077	Dren żółciowy 650 mm, FG 6, środkowo perforowany 70 mm (Neuhaus)	IIa
A	VK01101	Silikonowy okrągły dren 700 mm, FG 36, 15 otworów bocznych, 1 centralny, skośna krawędź, linia kontrastu RTG	IIa





# EC-Declaration of Conformity

ORIPLAST GmbH  
Hermannstraße 150 Industriegebiet  
66538 Neunkirchen  
Deutschland

Declare on sole responsibility that the following products

## Wound-Secretion-Management

- Class Is -

meet all provisions of Directive 93/42/EEG Annex V and is eligible to carry the mark



The individual products with their article numbers are listed in the appendix.

Notified Body:

DQS Medizinprodukte GmbH  
August-Schanz-Straße 21  
D - 60433 Frankfurt am Main

Expiry date: bis 09.01.2024

Neunkirchen, den 12.02.2021  
Ort, Datum

A handwritten signature in blue ink, reading 'A. Sauerwein'.

General Manager: Alexander Sauerwein

# Annex

## Declaration of Conformity

DMF A  
(Wound-Secretion-  
Management)  
Class Is

DMF	REF	Article	Risk
			Class
A	VK00001	Suction connecting tube 1800 mm, FG 33, one sided silicone connector, one sided finger tip (big)	Is
A	VK00005	Suction connecting tube 1800 mm, FG 18, one sided silicone connector 5 x 1,5 mm, one sided silicone connector 7 x 1,5 mm	Is
A	VK00006	Suction connecting tube 1800 mm, FG 18, one sided silicone connector, one sided LL male	Is
A	VK00007	Suction connecting tube 1000 mm, FG 27, both sided silicone connector	Is
A	VK00010	Silicone reservoir 100 ml, graduated	Is
A	VK00035	Distribution line adapter QL female, grommet	Is
A	VK00053	THORAFLEX I screw attachment for one bottle; patient tube with step connector, vacuum tube, marked rising tube (type Bulau)	Is
A	VK00054	THORAFLEX III screw attachment for one bottle; patient tube with step connector, vacuum tube, marked rising pipe, fixed above tube exit	Is
A	VK00055	THORAFLEX VI screw attachment for one bottle; patient tube (silicone), FG 36, step connector, vacuum tube, marked rising tube, tube reinforcement	Is
A	VK00056	THORAFLEX secretion collection system; screw attachment for one bottle; patient tube with step connector, vacuum tube, dripping pipe shortened and fixed	Is
A	VK00061	THORAFLEX VIII screw attachment for two bottles; patient tube with step connector, vacuum tube, marked rising tube, fixed dripping tube, connection tube	Is
A	VK00062	THORAFLEX screw attachment for two bottles; 2x patient tube with step connector, vacuum tube, fixed dripping tubes, 2x connecting tube	Is
A	VK00063	THORAFLEX XIV screw attachment for two bottles; patient tube with step connector, vacuum tube, HEIMLICH valve, fixed dripping tube, rising tube, suction control	Is
A	VK00064	THORAFLEX XXXII screw attachment with 2 bottles; 1000 ml, patient tube with step connector, vacuum tube, rising tube with control mark	Is
A	VK00066	THORAFLEX XXXVIII screw attachment for 2 bottles; patient tube with step connector, vacuum tube, connection tube, fixed dripping tube, rising tube, suction	Is
A	VK00075	THORAFLEX XXXII screw attachment with 3 bottles; 1000 ml, patient tube with step connector, vacuum tube	Is
A	VK00095	VENOFLEX 450 ml, 1080 mm, LL male, protection cap	Is
A	VK00096	ORIFLEX II replacement bottle 450 ml	Is
A	VK00097	ORIFLEX III replacement bottle 200 ml	Is
A	VK00102	Low Vacuum System bellow 350 ml, 1080 mm, non-return valve, QL connection; secretion bag 450 ml, non-return valve, bottom drain valve, Luer slip	Is
A	VK00104	Low Vacuum System bellow 350 ml, 1080 mm, non-return valve, QL connection; secretion bag 450 ml, non-return valve, bottom drain valve, Luer-Rekord slip	Is
A	VK00105	Low Vacuum System bellow 350 ml, 1080 mm, non-return valve, QL connection; without secretion bag	Is
A	VK00109	THORAFLEX bottle 1000 ml	Is
A	VK00111	Suction connecting tube 1900 mm, FG 40, one sided step connector	Is
A	VK00112	Suction connecting tube 2100 mm, FG 25, both sided funnel connector	Is
A	VK00113	Suction connecting tube 3000 mm, FG 25, both sided funnel connector	Is



## Annex

### Declaration of Conformity

DMF A  
(Wound-Secretion-  
Management)  
Class Is

A	VK00115	Suction connecting tube 3000 mm, FG 25, soft	Is
A	VK00119	Suction connecting tube 3000 mm, FG 25, one sided funnel connector	Is
A	VK00120	Suction connecting tube 3500 mm, FG 25, one sided funnel connector, one sided Sherwood connector	Is
A	VK00126	Suction connecting tube 1900 mm, FG 27, both sided silicone connector	Is
A	VK00127	Suction connecting tube 1300 mm, FG 27, both sided silicone connector	Is
A	VK00128	Suction connecting tube 1600 mm, FG 25, both sided silicone connector	Is
A	VK00129	Suction connecting tube 1500 mm, FG 25, both sided Sherwood connector, slide	Is
A	VK00130	Suction connecting tube 3000 mm, FG 27, one sided finger tip, one sided silicone	Is
A	VK00131	Suction connecting tube 1600 mm, FG 25, one sided finger tip, one sided silicone	Is
A	VK00135	Pleura puncture set 1500 ml, NRV, 900 mm, three-way stopcock blue, LL male; syringe 50 ml; without needle	Is
A	VK00230	HEIMLICH valve both sided step connector, LL male, HEIMLICH valve	Is
A	VK00231	Screw cap white, for Quick-Lock female	Is
A	VK00253	Distribution line 3-way screw connectors, LL female, step connector	Is
A	VK00254	Distribution line 4-way screw connectors, LL female, step connector	Is
A	VK00257	Distribution line 2-way screw connectors, 1650 mm with extension 200 mm, LL female, LL male, Sherwood connector	Is
A	VK00258	Distribution line 3-way screw connectors, 1650 mm with extension 200 mm, LL female, LL male, Sherwood connector with cap	Is
A	VK00259	Distribution line 3-way screw connectors, 1650 mm with extension 200 mm, LL female, QL connection, Sherwood connector with cap	Is
A	VK00261	Distribution line 3-way screw connectors, 1000 mm with extension 2000 mm, LL female, LL male, Sherwood connector with cap	Is
A	VK00262	Distribution line 3-way screw connectors, 1000 mm with extension 2000 mm, LL female, QL connection, Sherwood connector with cap	Is
A	VK00263	Distribution line 3-way screw connectors, 1650 mm with extension 70 mm, LL female, QL connection, Sherwood connector with cap	Is
A	VK00295	THORAFLEX Drainage System; screw attachment with one bottle, 1000 ml, patient tube with step connector, vacuum tube, HEIMLICH valve, marked rising tube	Is
A	VK00296	THORAFLEX XXXIV screw attachment with 2 bottles; 1000 ml, patient tube with step connector, vacuum tube, fixed dripping tube, marked rising tube	Is
A	VK00297	THORAFLEX XXXIX screw attachment with 2 bottles; 1000 ml, patient tube with step connector, vacuum tube, fixed dripping tube, suction control NRV	Is
A	VK00298	THORAFLEX XXXVIII screw attachment with 2 bottles; 1000 ml, patient tube with step connector, vacuum tube, suction control, NRV, tube reinforcement (blue)	Is
A	VK00308	ORIFLEX V replacement bottle 600 ml, QL	Is
A	VK00309	ORIFLEX V replacement bottle 600 ml, QL, cap	Is
A	VK00312	ORIFLEX V replacement bottle 600 ml, QL, self-adhesive stripe	Is
A	VK00314	ORIFLEX V 600 ml, 1080 mm, cut down connector, rubber/grommet	Is
A	VK00315	ORIFLEX V 600 ml, 1080 mm, cut down connector, QL connection	Is
A	VK00348	ORIFLEX IV replacement bottle 400 ml, QL	Is
A	VK00349	ORIFLEX IV replacement bottle 400 ml, QL, cap, self-adhesive stripe	Is
A	VK00351	ORIFLEX IV 400 ml, 1080 mm, cut down connector	Is
A	VK00352	ORIFLEX IV 400 ml, 1080 mm, cut down connector, QL connection	Is

# Annex

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DMF A  
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Class Is

A	VK00359	ORIFLEX IV 400 ml, 1080 mm, cut down connector, one slide clamp	Is
A	VK00368	ORIFLEX IV 400 ml, 1080 mm, cut down connector, QL connection, self-adhesive	Is
A	VK00372	ORIFLEX IV 400 ml, 1080 mm, screw connector, QL connection; self-adhesive stripe	Is
A	VK00378	Redon connecting tube - universal 1080 mm, cut down connector, for FG 6-18	Is
A	VK00383	Redon connecting tube - universal 1080 mm, cut down connector, rubber/grommet, for FG 6-18	Is
A	VK00384	Redon connecting tube - universal 1080 mm, cut down connector, slide clamp, QL, for FG 6-18	Is
A	VK00389	ORTHOFLEX II surgery drainage system (gravity) 450 ml, 1080 mm, screw connector, QL, LL female, filter 0.2 µm	Is
A	VK00390	ORIFLEX I 450 ml (50 % vacuum), 1080 mm, cut down connector, secretion stop	Is
A	VK00393	ORIFLEX I 450 ml, 1080 mm, screw connector, QL connection	Is
A	VK00394	ORIFLEX I 450 ml (50 % vacuum), 1080 mm, screw connector, QL connection	Is
A	VK00395	ORIFLEX I 450 ml (50 % vacuum) , 1080 mm, cut down connector, QL connection	Is
A	VK00396	ORTHOFLEX II replacement bottle (gravity) 450 ml, QL, LL female, filter 0.2 µm	Is
A	VK00398	ORIFLEX I replacement bottle 450 ml (50 % vacuum), LL male	Is
A	VK00399	ORIFLEX I replacement bottle 450 ml, QL	Is
A	VK00400	ORIFLEX I replacement bottle 450 ml (50% vacuum) , QL	Is
A	VK00405	ORIFLEX II replacement bottle 450 ml, QL, cap	Is
A	VK00409	ORIFLEX II replacement bottle 450 ml, QL	Is
A	VK00411	ORIFLEX II 450 ml, 1080 mm, cut down connector, secretion stop	Is
A	VK00412	ORIFLEX II 450 ml, 1080 mm, cut down connector, QL connection	Is
A	VK00426	ORIFLEX II 450 ml, 1080 mm, cut down connector, rubber/grommet, PVC free	Is
A	VK00428	ORIFLEX II 450 ml, 1080 mm, cut down connector, not disconnectable	Is
A	VK00429	ORIFLEX II 450 ml, 1080 mm, screw connector, rubber/grommet	Is
A	VK00431	ORIFLEX II 450 ml, 1080 mm, screw connector, QL connection	Is
A	VK00444	ORIFLEX II 450 ml, 1080 mm, screw connector, not disconnectable	Is
A	VK00454	ORIFLEX III 200 ml, 1080 mm, cut down connector, rubber/grommet	Is
A	VK00462	ORIFLEX III 200 ml, 1080 mm, cut down connector, not disconnectable	Is
A	VK00463	ORIFLEX III 200 ml, 1080 mm, screw connector, rubber/grommet	Is
A	VK00464	ORIFLEX III 200 ml, 1080 mm, screw connector, not disconnectable	Is
A	VK00465	ORIFLEX III 200 ml, 1080 mm, cut down connector, QL connection	Is
A	VK00466	ORIFLEX III 200 ml, 1080 mm, screw connector, QL connection	Is
A	VK00468	ORIFLEX III replacement bottle 200 ml (50% vacuum), QL	Is
A	VK00469	ORIFLEX III replacement bottle 200 ml, QL, cap	Is
A	VK00470	ORIFLEX III replacement bottle 200 ml, QL	Is
A	VK00476	Replacement bellows for Mini Pack 20 ml, cut down connector	Is
A	VK00483	Replacement bellows for Mini Pack 150 ml, cut down connector	Is
A	VK00484	Replacement bellows for Mini Pack 150 ml, universal connector	Is
A	VK00487	Low Vacuum System bellow 350 ml, 1080 mm, cut down connector, non-return valve, QL connection; secretion bag 450 ml, non-return valve, bottom drain valve	Is
A	VK00497	Low Vacuum System bellow 350 ml, 1080 mm, screw connector, non-return valve, QL connection; secretion bag 450 ml, non-return valve, bottom drain valve	Is
A	VK00505	Low Vacuum System bellow 350 ml, 1080 mm, srew connector, non-return valve, QL connection; without secretion bag	Is



## Annex

### Declaration of Conformity

DMF A  
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A	VK00515	Tube adapter 150 mm, 25 FG, both sided Sherwood connector	Is
A	VK00516	Suction connecting tube 2000 mm, FG 25, both sided Sherwood connector	Is
A	VK00518	Suction connecting tube 2400 mm, FG 25, both sided Sherwood connector	Is
A	VK00519	Suction connecting tube 3000 mm, FG 25 , both sided Sherwood connector	Is
A	VK00523	Suction connecting tube 3000 mm, FG 25, both sided Sherwood connector, soft	Is
A	VK00524	Suction connecting tube 3000 mm, FG 25, one sided Sherwood connector, one sided silicone connector	Is
A	VK00527	Suction connecting tube 1600 mm, FG 25, one sided Sherwood connector	Is
A	VK00529	Suction connecting tube 1600 mm, FG 25, one sided Sherwood connector, one sided finger tip	Is
A	VK00547	ORIFLEX III replacement bottle 200 ml, QL, vacuum indicator without scale division	Is
A	VK00548	ORIFLEX III 200 ml, 1080 mm, cut down connector, QL connection, vacuum indicator	Is
A	VK00549	ORIFLEX III 200 ml, 1080 mm, screw connector, QL connection, vacuum indicator	Is
A	VK00557	ORIFLEX IV 400 ml, 1080 mm, screw connector, QL connection	Is
A	VK00580	Tube adapter 75 mm, FG, 42 one sided step connector	Is
A	VK00582	Thorax drainage connector triple, 1600 mm, SH, step connectors, LL male, roberts	Is
A	VK00886	Y-connector 2x à 200 mm, 2x step connector; for thoracic drainage	Is
A	VK00892	Biliary drainage system 450 ml, NRV, bottom drain valve, pipette connector	Is
A	VK00916	Suction tube 280 mm, Y-connector	Is
A	VK00950	Fingertip with round surface	Is
A	VK00951	Fingertip with LL male	Is
A	VK00952	Fingertip with Luer slip	Is
A	VK01060	Suction tube 2200 mm, FG 25	Is