



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 13 10 66097 060

Manufacturer: **B. Braun Avitum AG**
Schwarzenberger Weg 73 - 79
34212 Melsungen
GERMANY

Facility(ies): B. Braun Avitum AG
Schwarzenberger Weg 73 - 79, 34212 Melsungen, GERMANY

B. Braun Avitum Saxonia GmbH
Juri-Gagarin-Strasse 13, 01454 Radeberg, GERMANY

Product Category(ies): **Dialyzers, Hemofilters, Hemodiafilters,
Dialysis Fluid Filters, Hemofilters for
Continuous Renal Replacement Therapy**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713029573

Valid from: 2014-01-02
Valid until: 2019-01-01

Date, 2014-01-03

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1

EC SERTIFIKATAS

Kokybės užtikrinimo sistema

(Medicinos priemonių 93/42/EEC direktyvos (MDD), II priedo išskyrus (4)
(Priemonių Klasė IIa, IIb ar III)

Nr.: G1 13 10 66097 060

Gamintojas:

B.Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Vokietija

Gamyklos:

B.Braun Avitum AG
Schwarzenberger Weg 73-79, 34212 Melsungen, Vokietija

B.Braun Avitum Saxonia GmbH
Juri-Gagarin-Strasse 13, 01454 Radeberg, Vokietija

Produkto kategorija

**Dializatoriai, Hemofiltraai, Hemodiafiltraai,
Dializės skysčių filtraai, hemofiltraai tęstinei inkstų pakaitinei
terapijai**

TUV Product Service GmbH sertifikavimo įstaiga patvirtina, kad nurodytas gamintojas įdiegė kokybės užtikrinimo sistemą pagal MDD dėl medicinos įrenginių II priedo numatytų gaminių ir kitų kategorijų kūrimo, gamybos ir galutinio patikrinimo. Ši kokybės užtikrinimo sistema atitinka šios Direktyvos nuostatas ir yra nuolat stebima. Norint platinti III klasės gaminius būtina gauti papildomą II(4) priede numatytą sertifikatą. Taip pat žr.pastabas kitoje lapo pusėje.

Pranešimo Nr.: 713029573

Galioja nuo: 2014-01-02

Galioja iki: 2019-01-01

Data 2014 01 03

/Parašas/

Hans-Heiner Junker

TÜV SUD Product Service GbmH yra oficiali tarnyba, Identifikacijos Nr. 0123.

Puslapis 1 iš 1

TÜV SUD Product Service GmbH, Sertifikavimo tarnyba, Ridlerstrasse 65, 80339 Miunchenas, Vokietija

Wir

We

**B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**- Diacap®
- xevonta
Hämodialysatoren, Hämofilter
Hämodiafilter**

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden
Richtlinie übereinstimmt/übereinstimmen:Richtlinie 93/42/EWG des Rates vom
14. Juni 1993 über Medizinprodukte**Konformitätsbewertungsverfahren:**
nach Anhang II Absatz 3
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der oben genannten
Richtlinie:
Klasse IIb, Regel 3**EG-Zertifikat Nr.**
G1 09 01 66097 021
Benannte Stelle:TÜV Product Service GmbH
Kennnummer 0123**Datum der ersten CE-Kennzeichnung:**
2001-06hereby declare in our own responsibility
that the product/s**- Diacap®
- xevonta
Haemodialyzers, Haemofilters,
Haemodiafilters**

(article numbers see attachment I)

is/are in compliance with the following
directive:Council Directive 93/42/EEC of 14 June 1993
concerning medical devices**Conformity assessment procedure:**
according to annex II clause 3
of the Directive named above**Classification**
according to annex IX of the Directive named
above:
Class IIb, Rule 3**EC Certificate No.**
G1 09 01 66097 021
Notified body:TÜV Product Service GmbH
Identification number 0123**Date of first CE-marking:**
2001-06

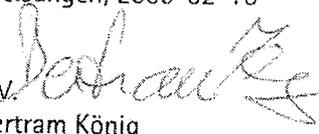
Melsungen, 2009-02-16


Dr. Wolfgang Feller
Member of the Executive Board

Mirandola, 2009-02-16


Dr. Giuliana Gavioli
Head of Division RA

Melsungen, 2009-02-16


i. V. Bertram König
Vice President Quality

EB ATITIKTIES DEKLARACIJA

Mes

B.Braun Avitum AG
Schwarzenberger Weg 73-79,
34212 Melsungen
Vokietija

prisiimdami atsakomybę pareiškiame, kad šie produktai

-Diacap
-xevonta

Hemodializatoriai, Hemofiltrai,
Hemodiafiltrai

(artikulų numerius žiūrėkite priede Nr.1)
atitinka sekančią Direktyvą:

Medicinos priemonių direktyva 93/42/EEC
1993 m. birželio 14 d.

Atitikties patvirtinimo procedūra:
Pagal priedo II punktą 3 pažymėtą aukščiau

Klasifikacija
pagal priedą IX direktyvoje pažymėtą aukščiau:
Klasė II b, taisyklė 3

EB sertifikatas:
G1 09 01 66097 021

Registravimo tarnyba:
TUV Product Service GmbH
Identifikacijos Nr. 0123

Pirmo pažymėjimo data:
2001-06



Melsungen, 2009-02-16

/parašas/
Dr. Wolfgang Feller
(Valdybos narys.)

Mirandola, 2009-02-16

/parašas/
Dr. Giuliana Gavioli
(RA padalinio vadovas)

Melsungen, 2009-02-16

/parašas/
Bertram Konig
(Viceprezidentas kokybei.)

Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description
7203525	Diacap® α Polysulfone LO PS 10
72035250	Diacap® α Polysulfone LO PS 10
7203533	Diacap® α Polysulfone LO PS 12
72035330	Diacap® α Polysulfone LO PS 12
7203541	Diacap® α Polysulfone LO PS 15
72035410	Diacap® α Polysulfone LO PS 15
7203550	Diacap® α Polysulfone LO PS 18
72035500	Diacap® α Polysulfone LO PS 18
7203568	Diacap® α Polysulfone LO PS 20
72035680	Diacap® α Polysulfone LO PS 20
7203622	Diacap® α Polysulfone HI PS 10
72036220	Diacap® α Polysulfone HI PS 10
7203630	Diacap® α Polysulfone HI PS 12
72036300	Diacap® α Polysulfone HI PS 12
7203649	Diacap® α Polysulfone HI PS 15
72036490	Diacap® α Polysulfone HI PS 15
7203657	Diacap® α Polysulfone HI PS 18
72036570	Diacap® α Polysulfone HI PS 18
7203665	Diacap® α Polysulfone HI PS 20
72036650	Diacap® α Polysulfone HI PS 20
7203673	Diacap® α Polysulfone+ HiFlo 18
72036730	Diacap® α Polysulfone+ HiFlo 18
7203681	Diacap® α Polysulfone+ HiFlo 23
72036810	Diacap® α Polysulfone+ HiFlo 23
720 4525	xevonta Lo 10
720 4533	xevonta Lo 12
720 4541	xevonta Lo 15
720 4550	xevonta Lo 18
720 4568	xevonta Lo 20
720 4570	xevonta Lo 23
720 4622	xevonta Hi 10
720 4630	xevonta Hi 12
720 4649	xevonta Hi 15
720 4657	xevonta Hi 18
720 4665	xevonta Hi 20
720 4670	xevonta Hi 23

EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

We

B. Braun Medizintechnologie GmbH, Schwarzenberger Weg 73-79, D-34212 Melsungen

hereby declare under our own responsibility that the products

**Diacap® Ultra
dialysis fluid filter**

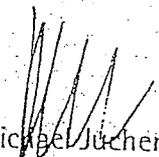
whom this declaration refers to, are in compliance with the following Directive:

**Medical Device Directive 93/42/EEC
June 14, 1993**

through the certificate: G1 04 02 21273 032

Diacap® Ultra are class IIa medical devices according to rule 3 of MDD 93/42/EEC - Annex IX

The list of product article numbers is provided in Attachment.


Dr. Michael Juchem
(Marketing)
Dr. Giufana Gavioli
(Regulatory Affairs)
Dr. Günter Koppensteiner
(Quality Management)Glandorf, 01.03.2004Mirandola, 3.03.04Melsungen, 2004.02.26

Art. No. 7107365 Diacap® Ultra


Dr. Michael Juchem
(Marketing)


Dr. Gioviana Gavioli
(Regulatory Affairs)


Dr. Günter Koppensteiner
(Quality Management)

EB ATITIKTIES DEKLARACIJA MEDICINOS PRIEMONĖMS

Mes

B.Braun Medizintechnologie GmbH, Schwarzenberger Weg 73-79, D-34212 Melsungen

prisiimdami atsakomybę pareiškiame, kad šis produktas

Diacap Ultra dializės skysčių filtras

kuriam taikoma ši deklaracija, atitinka sekančią Direktyvą:

Medicinos priemonių direktyva 93/42/EEC
1993 m. birželio 14 d.

pagal sertifikata: G1 04 02 21273 032

Diacap Ultra yra priskirti IIa medicinos priemonėms pagal MDD 93/42/EEC 3 taisyklę - IX priedas.

Pridedamas produktų sąrašas.

/parašas/
Dr. Michael Juchem
(Marketingo sk.)

Glandorf, 2004 03 01

/parašas/
Dr. Giuliana Gavioli
(Registracijos sk.)

Mirandola, 2004 03 03

/parašas/
Dr. Gunter Kooensteiner
(Kokybės vadybos sk.)

Melsungen, 2004 02 26

Art.Nr. 7107365 Diacap Ultra

/parašas/
Dr. Michael Juchem
(Marketingo ir vystymo sk.)

/parašas/
Giuliana Gavioli
(Registracijos sk.)

/parašas/
Dr. Gunter Koppensteiner
(Kokybės vadybos sk.)



Product Service

EC - CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 10 05 66097 031

Manufacturer:**B. Braun Avitum AG**

Schwarzenberger Weg 73 - 79
34212 Melsungen
GERMANY

Facility(ies):

B. Braun Avitum AG
Schwarzenberger Weg 73 - 79, 34212 Melsungen, GERMANY

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11, 41037 Mirandola (MO), ITALY

B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

**Product
Category(ies):****Lines for Dialysis and Hemo(dia)filtration**

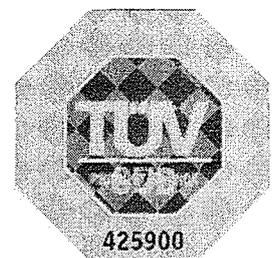
The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: 71368620

Valid until: 2015-06-22

Date, 2010-06-23

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

Page 1 of 1

EC SERTIFIKATAS

Kokybės užtikrinimo sistema

(Medicinos priemonių 93/42/EEC direktyvos II priedo 3 skyrius)

Nr.: G1 10 05 66097 031

Gamintojas: **B.Braun Avitum AG**
Schwarzenberger Weg 73-79
34212 Melsungen
Vokietija

Gamykla (-os): B.Braun Avitum AG
Schwarzenberger Weg 73-79, 34212 Melsungen, Vokietija

B.Braun Avitum Italy S.p.A
Via XXV Luglio, 11, 41037 Mirandola (MO), Italija

B.Braun Medical Kft. Produkcijos skyrius
Deli-Kulhatar g.2-4, 3200 Gyongyos, Vengrija

Produkto (-ų) kategorija (-jos) **Linijos dializei ir hemodiafiltracijai**

TUV Product Service GmbH sertifikavimo įstaiga patvirtina, kad nurodytas gamintojas įdiegė Direktyvos 93/42/EEB dėl medicinos įrenginių II priedo 3 dalyje numatytų gaminių ir jų kategorijų kūrimo, gamybos ir galutinio patikrinimo kokybės užtikrinimo sistemą. Ši kokybės užtikrinimo sistema atitinka šios Direktyvos nuostatas ir yra nuolat stebima. Norint platinti II klasės gaminius būtina gauti papildomą II.4 priede numatytą sertifikatą. Taip pat žr.pastabas kitoje lapo pusėje.

Pranešimo Nr.: 71368620

Galioja iki: 2015 06 22

Data 2010 06 23 /Parašas/
Hans-Heiner Junker



Terlece
Doklodu konceptai
ir mediana
Amigjes darys
Rol

TÜV PRODUCT SERVICE GMBH yra oficiali tarnyba, veikianti pagal tarybos medicininės įrangos direktyvą 93/42/EEC. Identifikacijos Nr. 0123.

Puslapis 1 iš 1

TÜV PRODUCT SERVICE GMBH, Sertifikavimo tarnyba, Ridlerstrasse 65, D-80339 Miunchenas

Wir

We

**B. Braun Medizintechnologie GmbH
Schwarzenberger Weg 73-79
34212 Melsungen
Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**Blutschlauchsysteme für die Hämodialyse**

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen:Richtlinie 93/42/EWG des Rates vom
14. Juni 1993 über Medizinprodukte**Konformitätsbewertungsverfahren:**
nach Anhang II Absatz 3
der oben genannten Richtlinie**Klassifizierung**

gemäß Anhang IX der oben genannten Richtlinie:

- siehe Anhang -

EG-Zertifikat Nr.G1 05 05 21273 039
G2S 03 02 21273 017**Benannte Stelle:**TÜV Product Service GmbH
Kennnummer 0123**Datum der ersten CE-Kennzeichnung:**

1998-02

hereby declare in our own responsibility
that the product/s**Bloodline Systems for Haemodialysis**

(article numbers see attachment I)

is/are in compliance with the following directive:

Council Directive 93/42/EEC of 14 June 1993
concerning medical devices**Conformity assessment procedure:**
according to annex II clause 3
and to annex V
of the Directive named above**Classification**according to annex IX of the Directive named
above:

- see attachment -

EC Certificate No.G1 05 05 21273 039
G2S 03 02 21273 017**Notified body:**TÜV Product Service GmbH
Identification number 0123**Date of first CE-marking:**

1998-02

Melsungen, 2007-03-31


Dr. Wolfgang Feller
Managing Director

Mirandola, 2007-03-31


Dr. Giuliana Gavioli
Head of Division RA

Melsungen, 2007-03-31


i.A. Dr. Thomas Beuttler
Head of Division QM

B | BRAUN

ATITIKTIES DEKLARACIJA

Padalinys RA
Dok.: 38/04-RA-sz
Data : 2004 05 26
Patikr.: 1
Patikrinimo data: 2005 06 14
Psl. 1 iš 5

Mes

B.Braun Medizintechnologie GmbH,
Schwarzenberger Weg 73-79,
D-34212 Melsungen
Vokietija

prisiimdami atsakomybę, pareiškiame, kad šis produktas/-ai

Kraujo linijų sistemos hemodializei

kuriam/-iems taikoma ši deklaracija, atitinka sekančią direktyvą:

93/42/EEC Tarybos direktyva
1993 m. birželio 14 d.
apie medicinos priemonės

Atitikties vertinimo procedūra
pagal aukščiau paminėtos direktyvos II priedo 3 d.

Klasifikacija
pagal aukščiau paminėtos direktyvos IX priedą

EC Sertifikato Nr.
G1 05 05 21273 039
G2S 03 02 21273 017

Notifikuota:
TUV rodect service GmbH
Identifikacijos nr.0123

Pirmoji CE žymėjimo data
1998 02



*Delektoides komercijai
ir medicinai
Remigijus Dacypas
R. D.*

Melsungenas, 2005 06 14
/Parašas/

Dr. Wolfgang Feller
Generalinis direktorius

Mirandola, 2005 06 14
/Parašas/

Dr. Giuliana Gavioli
RA padalinio vadovė

Melsungenas, 2005 06 14
/Parašas/

Birgit Unger
QM padalinio vadovė

Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class
721055A	HDF on-line tubing	Ila
7011814	Venous line for HP 50	Ila
7020228	Substitution pumpenleitung line HD Secura	Ila
7020246	Diafusine line – Diafusine Leitung	Ila
7020250	Substitution line for Dialog	Ila
7020457	Kochsalzbeutel leer 2000 ml	Ila
7029110	Überleitungsgerät Luer F. 2 ampullen	Ila
7034601	A/V set for Dialog	Ila
7034628	A/V set for Dialog	Ila
7035136	Cross over arterial bloodline for HD Secura	Ila
7035411	Arterial bloodline for HD Secura	Ila
7036086	Cross over venous bloodline for HD Secura	Ila
7036221	Venous bloodline for HD secura	Ila
7036604	A/V set for Dialog	Ila
7037212	A/V set for HD Secura	Ila
7037228	A/V set for HD secura	Ila
7037236	A/V set for HD secura	Ila
7037279	A/V set for HD secura	Ila
7039360	A/V set for Gambro AK90	Ila
7039510	A/V set for Miro 1HP	Ila
7039533	A/V set for Miroclav	Ila
7039603	A/V set for MTS 200B C+E	Ila
7039611	A/V set for MTS	Ila
7039620	A/V set for MTS 200B C+E / 400B	Ila
7039646	A/V set for MTS	Ila
7039700	A/V Set for Integra	Ila
7039808	A/V set for Gambro/Althin/Fresenius/Dialog	Ila
7070012	Arterial bloodline for Trio	Ila
7070020	Arterial bloodline with chamber for Trio	Ila
7070217	Substitution/filtration line for Trio	Ila
7070225	Warming line for CVWH	Ila
7070233	Warming line Astotube	Ila
7070420	Adapter	Ila
7070438	Y connecting line for Trio	Ila
7210143	A/V set for HD Secura	Ila
7210273	Cross-over venous bloodline for Dialog	Ila
7210274	Cross-over arterial bloodline for Dialog	Ila
7210275	Substitution line for Dialog	Ila
7210312	Substitution line for Dialog	I sterile
7210318	Cross over arterial bloodline with infusion set for Dialog	Ila
7210319	Cross over venous bloodline for Dialog	Ila

7210337	A/V set for Dialog	Ila
7210426	A/V set for Miroclav	Ila
7210558	HDF on-line tubing	Ila
7210559	Adapter for predilution	Ila
7210583	A/V set for Gambro/ Althin/ Fresenius/ Dialog	Ila
7210588	A/V set "no DOP PVC"	Ila
7210589	Substitution Line for Dialog	Ila
7210602	A/V set for Gambro AK100/AK200	Ila
7210603	A/V set for Gambro AK100/AK200 (SN)	Ila
7210604	A/V set for Nikkiso DBB03	Ila
7210605	A/V set for Nikkiso DBB03 (SN)	Ila
7210606	A/V set for FMC 2008/4008	Ila
7210607	A/V set for FMC (SN II) 2008/4008	Ila
7210610	Cross Over A/V set for Dialog	Ila
7210611	Cross Over A/V set for Dialog	Ila
7210645	Single needle valve A/V set	Ila
7210684	A/V set for Dialog	Ila
7210684M	A/V set for Dialog	Ila
7210687	A/V set for Althin	Ila
7210690	Adapter by pass	Ila
7210697	A/V set with infusion set and recirculation connector for Dialog	Ila
7210698	Cross over A/V set with infusion set and recirculation connector for Dialog	Ila
7210713	A/V set for Dialog	Ila
7210714	A/V set single needle for Dialog	Ila
7210717	A/V set for HD Secura single needle	Ila
7210734	A/V set for Gambro, Althin, Fresenius Dialog	Ila
7210785	A/V set for Dialog	Ila
7011270	Y connector	Ila
PP001681	Low volume A/V set for dialog	Ila
PP001898	Adapter	Ila
7210208	Venous bloodline	Ila
7210353	Arterial bloodline	Ila
7210357	Substitution / dialysate inlet line	Ila
7210358	Ultrafiltration / dialysate outlet line	Ila
7210631	7000 ml collecting bag	Isterile
7210637	Ultrafiltration / dialysate outlet line	Ila
7210636	Substitution / dialysate inlet line	Ila
7210298	7000 ml collecting bag	Isterile
7210008	Bag connectionline	Ila
7210362	Ultrafiltration line	Ila
7210359	Single needle venous bloodline	Ila
7210360	Substitution line	Ila
7210361	Single needle ultrafiltration line	Ila
7210654	7000 ml collecting bag	Isterile
7210349	Diapact CRRT Hemofiltration-Haemodialysis kit	Ila
7210635	Diapact CRRT Hemofiltration/Haemodialysis High Volume kit	Ila

7210492	Diapact CRRT Hemofiltration-Haemodialysis kit	Ila
7210657	Diapact CRRT High Flux Dialysis Recirculation kit	Ila
7210351	Diapact CRRT Slow Continuous Ultrafiltration kit	Ila
7210350	Diapact CRRT Single Needle Hemofiltration Kit	Ila
7210807	A/V Set for Dialog, Gambro, Althin, Fresenius,	Ila
72106120	A/V Set for Gambro	Ila
72106121	A/V Set for FMC MTS	Ila
72106123	A/V Set SN for Gambro AK	Ila
72106125	A/V Set for HDF for Gambro AK	Ila
72106126	A/V Set for Nikkiso DBB (R)	Ila
72106127	A/V Set SN for Nikkiso DBB (R)	Ila
72106128	A/V Set for FMC Gambro/Hospal)	Ila



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 09 66097 064

Manufacturer:

B. Braun Avitum AG

Schwarzenberger Weg 73 - 79
34212 Melsungen
GERMANY

Facility(ies):

Kawasumi Laboratories (Thailand) Co., Ltd. (KLT-3)
Nava Nakorn Industrial Promotion Zone, 55/26 MU 13, Phahon
Yothin Road, KM-46, Tambon Khlong Nueng, Amphoe Khlong
Luang, Changwat Pathum Thani 12120, THAILAND

Kawasumi Laboratories (Thailand) Co., Ltd. (KORAT)
48 MU 8, Ratchasima-Chok Chai Road, Tambon Tha Ang,
Amphoe Chok Chai, Changwat Nakhon Ratchasima 30190,
THAILAND

Kawasumi Laboratories (Thailand) Co., Ltd. (KLT-4)
Nava Nakorn Industrial Promotion Zone, 55/27 MU 13, Phahon
Yothin Road, KM-46, Tambon Khlong Nueng, Amphoe Khlong
Luang, Changwat Pathum Thani 12120, THAILAND

Kawasumi Laboratories (Thailand) Co., Ltd. (KLT-3B)
Nava Nakorn Industrial Promotion Zone, 55/26 MU 13, Phahon
Yothin Road, KM-46, Tambon Khlong Nueng, Amphoe Khlong
Luang, Changwat Pathum Thani 12120, THAILAND

Product

A. V. Fistula Needles

Category(ies):

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

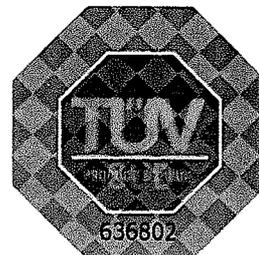
Report No.: 713049303

Valid from: 2015-03-22

Valid until: 2020-03-21

H.-H. Junker

Hans-Heiner Junker



Date, 2015-03-12

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1

EC SERTIFIKATAS

Kokybės užtikrinimo sistema

(Direktyva 93/42/EEB dėl medicinos įrenginių(MDD) II priedo išskyrus (4)
(Įrenginių Iia, Iib ar III klasės)

Nr.: G1 14 09 66097 064

Gamintojas:

B.Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Vokietija

Gamykla (os):

Kawasumi Laboratories (Thailand) Co., Ltd. (KLT-3)
Nava Nakom Industrial Promotion Zone, 55/26 MU-13,
Phahon Yothin Rd., KM-46, Tambon Khlong Nueng, Amphoe
Khlong Luang, Changwat Pathun Thani 12120, Tailandas

Kawasumi Laboratories (Thailand) Co., Ltd. (KORAT)
48 MU-8, Ratchasima-Chokchai Rd., Tambon Tha-Ang, Amphoe
Chokchai, Changwat Nakhon Ratchasima 30190, Tailandas

Kawasumi Laboratories (Thailand) Co., Ltd. (KLT-4)
Nava Nakom Industrial Promotion Zone, 55/27 MU-13,
Phahon Yothin Rd., KM-46, Tambon Khlong Nueng, Amphoe
Khlong Luang, Changwat Pathun Thani 12120, Tailandas

Kawasumi Laboratories (Thailand) Co., Ltd. (KLT-3B)
Nava Nakom Industrial Promotion Zone, 55/26 MU-13,
Phahon Yothin Rd., KM-46, Tambon Khlong Nueng, Amphoe
Khlong Luang, Changwat Pathun Thani 12120, Tailandas

Produkto kategorija(os): A.V. fistulinės adatos

TUV Product Service GmbH sertifikavimo įstaiga patvirtina, kad nurodytas gamintojas įdiegė medicinos įrenginių II priede numatytų gaminių ir jų kategorijų kūrimo, gamybos ir galutinio patikrinimo kokybės užtikrinimo sistemą. Ši kokybės užtikrinimo sistema atitinka šios Direktyvos nuostatas ir yra nuolat stebima. Norint platinti III klasės gaminius būtina gauti papildomą II.4 priede numatytą sertifikatą. Taip pat žr.pastabas kitoje lapo pusėje.

Pranešimo Nr.: 713049303

Galioja nuo: 2015-03-22

Galioja iki: 2020 03 21

Data 2015 03 12

/Parašas/
Hans-Heiner Junker

TÜV PRODUCT SERVICE GMBH yra oficiali tarnyba, veikianti pagal tarybos medicininės įrangos direktyvą 93/42/EEC. Identifikacijos Nr. 0123.

Puslapis 1 iš 1

TÜV PRODUCT SERVICE GMBH, Sertifikavimo tarnyba, Ridlerstrasse 65, D-80339 Munchenas, Vokietija



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 12 10 66097 050

Manufacturer: **B. Braun Avitum AG**
Schwarzenberger Weg 73 - 79
34212 Melsungen
GERMANY

Product Category(ies): **Sterile and non-sterile hemodialysis concentrates (class IIb), solid dosage form for hemodialysis (class IIb), and irrigation solutions (class IIa)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713012956

Valid from: 2013-02-17
Valid until: 2018-02-16

Date, 2013-02-15

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Product Service

EC Certificate**Full Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 12 10 66097 050**Facility(ies):**

B. Braun Avitum AG, Werk Glandorf
Kattenvenner Straße 32, 49219 Glandorf, GERMANY

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11, 41037 Mirandola (MO), ITALY

EC SERTIFIKATAS

Kokybės užtikrinimo sistema

(Medicinos priemonių 93/42/EEC direktyvos (MDD), II priedo išskyrus (4)
(Priemonių Klasė IIa, IIb ar III)

Nr.: G1 12 10 66097 050

Gamintojas:

B.Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Vokietija

Produkto kategorija

**Sterilūs ir nesterilūs hemodializės koncentratai (klasė IIb),
sauso dozavimo formos hemodializei (klasė IIb) ir
irigaciniai tirpalai (klasė IIa)**

TUV Product Service GmbH sertifikavimo įstaiga patvirtina, kad nurodytas gamintojas įdiegė kokybės užtikrinimo sistemą pagal MDD dėl medicinos įrenginių II priedo numatytų gaminių ir jų kategorijų kūrimo, gamybos ir galutinio patikrinimo. Ši kokybės užtikrinimo sistema atitinka šios Direktyvos nuostatas ir yra nuolat stebima. Norint platinti III klasės gaminius būtina gauti papildomą II(4) priede numatytą sertifikatą. Taip pat žr.pastabas kitoje lapo pusėje.

Pranešimo Nr.: 713012956

Galioja nuo: 2013-02-17

Galioja iki: 2018-02-17

Data 2013 02 15 /Parašas/
Hans-Heiner Junker

TÜV SUD Product Service GmbH yra oficiali tarnyba, Identifikacijos Nr. 0123.

Puslapis 1 iš 2

TÜV SUD Product Service GmbH, Sertifikavimo tarnyba, Ridlerstrasse 65, 80339 Miunchenas, Vokietija

EC SERTIFIKATAS

Kokybės užtikrinimo sistema

(Medicinos priemonių 93/42/EEC direktyvos (MDD), II priedo išskyrus (4)
(Priemonių Klasė Iia, Iib ar III)

Nr.: G1 12 10 66097 050

Gamykla(-os):

B.Braun Avitum AG, Werk Glandorf
Kattenvenner Str.32,49219 Glandorf, Vokietija

B.Braun Avitum Italy.
Via XXV Luglio,11, 41037 Mirandola (MO), Italija

Tikras:
Dezinfekcinis kompozicinis ir
medicininis šampūnas
deinergalys
A. Š.



Wir

We

**B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**Saure Bicarbonat-Hämodialyse-Konzentrate**
(Artikelnummern siehe Anlage I)mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen:Richtlinie 93/42/EWG des Rates vom
14. Juni 1993 über Medizinprodukte**Konformitätsbewertungsverfahren:**
nach Anhang II Absatz 3
der oben genannten Richtlinie**Klassifizierung**

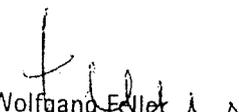
gemäß Anhang IX der oben genannten Richtlinie:

Klasse IIb Regel 3
Klasse I sterile Regel 1
EG-Zertifikat Nr.
G1 08 03 66097 004
G2S 08 03 66097 001**Benannte Stelle:**
TÜV Product Service GmbH
Kennnummer 0123**Datum der ersten CE-Kennzeichnung:**
1998-09hereby declare in our own responsibility
that the product/s**Acidic Bicarbonate Haemodialysis Concentrates**
(article numbers see attachment I)

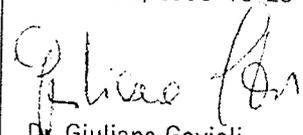
is/are in compliance with the following directive:

Council Directive 93/42/EEC of 14 June 1993
concerning medical devices**Conformity assessment procedure:**
according to annex II section 3
of the Directive named above**Classification**according to annex IX of the Directive named
above:Class IIb rule 3
Class I sterile Rule 1
EC Certificates No.
G1 08 03 66097 004
G2S 08 03 66097 001**Notified body:**
TÜV Product Service GmbH
Identification number 0123**Date of first CE-marking:**
1998-09

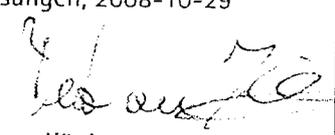
Melsungen, 2008-10-29


Dr. Wolfgang Fellet
Member of the Executive Board

Mirandola, 2008-10-29


Dr. Giuliana Gavioli
Head of Division RA

Melsungen, 2008-10-29


i. V. Betram König
Vice President Quality

Padalinys RA
Dok.: 71/04-RA-sz
Data : 2004 08 27
Patikr.: 8
Patikrinimo data: 2008 10 29
Psl. 1 iš 10

Mes

B.Braun Avitum AG,
Schwarzenberger Weg 73-79,
D-34212 Melsungen
Vokietija

prisiimdami atsakomybę, pareiškiame, kad šis produktas/-ai

Rūgštiniai bikarbonatiniai hemodializės koncentratai

kuriam/-iems taikoma ši deklaracija, atitinka sekančią direktyvą:

93/42/EEC Tarybos direktyva
1993 m. birželio 14 d.
apie medicinos priemonės

Atitikties vertinimo procedūra
pagal aukščiau paminėtos direktyvos II priedo 3 d.

Klasifikacija
pagal aukščiau paminėtos direktyvos IX priedą

EC Sertifikato Nr.
G1 08 03 66097 004
G2S 08 03 66097 001

Notifikuota:
TUV roduct service GmbH
Identifikacijos nr.0123

Pirmoji CE žymėjimo data
1998 09

Telma:
Dra. Bronius Komarova
ir medicinosi
Romipus Kociuska



Melsungenas, 2008 10 29
/Parašas/

Dr. Wolfgang Feller
Valdybos narys

Mirandola, 2008 10 29
/Parašas/

Dr. Giuliana Gavioli
RA padalinio vadovė

Melsungenas, 2008 10 29
/Parašas/

Betram Konig
Viceprzidentas kokybei

CE – Declaration of Conformity

EG – Konformitätserklärung

We / Wir

B. Braun Medizintechnologie GmbH

Schwarzenberger Weg 73-79

D - 34212 Melsungen

Site

Fertigungsstätten

B.Braun Medizintechnologie GmbH Werk Glandorf

D - 49219 Glandorf

B.Braun Medizintechnologie GmbH Werk Bremerhaven

D - 27568 Bremerhaven

declare in our own responsibility, that the product/s
erklären in eigener Verantwortung, daß das Produkt/die Produktkategorie

Alkaline Bicarbonate Haemodialysis Concentrates

Basische Bicarbonat-Hämodialyse-Konzentrate

which is covered by this declaration is in compliance with the following
directives/standards:

*auf die sich diese Erklärung bezieht, mit den folgenden Richtlinien/Gesetzen/Normen über-
einstimmt:*

Council Directive 93/42/EEC

of 14 June 1993

concerning Medical Devices

Richtlinie 93/42/EWG des Rates

vom 14. Juni 1993

über Medizinprodukte

Glandorf, 14.05.03

ppa.



Dr. Martin Renken

ATITIKTIES DEKLARACIJA

Mes

B.Braun Medizintechnologie GmbH,
Schwarzenberger Weg 73-79,
D-34212 Melsungen

Vieta

B.Braun Medizintechnologie GmbH Werk Glandorf
D-49219 Glandorf

B.Braun Medizintechnologie GmbH Werk Bremerhaven
D-27568 Bremenhaven

prisiimdami atsakomybę, pareiškiame, kad šis produktas/ai

Šarminis bikarbonatinis hemodializės koncentratas

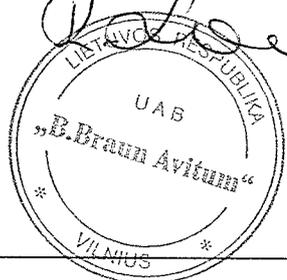
kuriam taikoma ši deklaracija, atitinka sekančias direktyvas/ standartus

93/42/EEC Tarybos direktyva
1993 m. birželio 14 d.
apie medicinos priemonės

Glandorf, 2003 05 14

/parašas/
Dr.Martin Renken

Tetara:
Diakarbonis koncentratas
medicinai
koncentratas
Dr. Martin Renken



LIETUVOS RESPUBLIKA
UAB
„B. Braun Avitum“
VILNIUS

Anlage I / Attachment I**Hemodialysis Concentrate Class IIb**

Art.-Nr. / Art. No.	Artikelbezeichnung Article description	
590	SW 56 BC	10 L
297	SW 74 A	10 L
367	SW 74 A	800 l
3356	SW 75 A	300 l
305	SW 79 A	10 L
227	SW 79 A	300 L
7820	SW 93 A	5 L
3269	SW 93 A	6 L
163	SW 93 A	800 L
349	SW 93 A	10 L
7831	SW 95 A	5 L
17	SW 95 A	6 L
7959	SW 95 A	6 L (5 L F.)
149	SW 95 A	10 L
362	SW 95 A	300 L
7233	SW 95 A	500 L
361	SW 95 A	800 L
7949	SW 95 A Baxter	6 L
201	SW 101 A	10 L
7832	SW 102 A	5 L
565	SW 102 A	300 L
171	SW 102 A	800 L
7714	SW 102 A	6 L
147	SW 102 A	10 L
211	SW 105 A	10 L
7415	SW 105 A	300 L
3283	SW 105 A	800 L
896	SW 121 A	10 L
7210886	SW 127 A	5 L
7210765	SW 127 A	5,5 L Bag
887	SW 127 A-F	6 L
7578	SW 127 A	10 L
204	SW 127 A	300 L
7278	SW 127 A	500 L
7778	SW 127 A	6 L
7953	SW 127 A	6 L (5 L F.)
7961	SW 127 A	8 L (7 L F.)
7960	SW 127 A	8 L
7178	SW 127 A	800 L
7934	SW 127 A Baxter	6 L
165	SW 128 A	10 L
7416	SW 128 A	300 L
7968	SW 128 A	800 L
7834	SW 130 A	5 L
107	SW 130 A	800 L
143	SW 130 A	10 L
359	SW 130 A	6 L
7210884	SW 139 A	5 L
7210764	SW 139 A	5,5 L Bag

Art.-Nr. / Art. No.	Artikelbezeichnung Article description
7821	SW 139 A 5 L
7524	SW 139 A 10 L
7324	SW 139 A 300 L
7224	SW 139 A 500 L
7724	SW 139 A 6 L
364	SW 139 A 800 L
7939	SW 139 A Baxter 6 L
291	SW 148 A 800 L
344	SW 152 A 300 L
332	SW 152 A 800 L
556	SW 152 A 10 L
7837	SW 154 A 5 L
7713	SW 154 A 6 L
253	SW 154 A 10 L
3357	SW 154 A 300 L
3212	SW 154 A 800 L
3336	SW 156 A 10 L
3230	SW 156 A 300 L
585	SW 156 A 800 L
262	SW 159 A 10 L
582	SW 162 A 10 L
7822	SW 163 A 5 L
3203	SW 163 A 10 L
7246	SW 163 A 500 L
8473	SW 163 A 6 L
11	SW 166 A 300 L
8475	SW 166 A 6 L
7282	SW 166 A 500 L
335	SW 166 A 10 L
7430	SW 166 A 800 L
160	SW 167 A 300 L
156	SW 167 A 800 L
247	SW 171 A 10 L
7823	SW 172 A 5 L
7823	SW 172 A 5 L
103	SW 172 A 300 L
577	SW 172 A 10 L
517	SW 172 A 6 L
7283	SW 172 A 500 L
7836	SW 173 A 5 L
7712	SW 173 A 6 L
595	SW 173 A 10 L
7210763	SW 178 A 5,5 L Bag
7824	SW 178 A 5 L
137	SW 178 A 10 L
138	SW 178 A 300 L
139	SW 178 A 500 L
133	SW 178 A 6 L
3221	SW 181 A 10 L
3226	SW 182 A 10 L
7435	SW 184 A 6 L
3228	SW 184 A 800 L
3227	SW 184 A 10 L
8478	SW 192 A 6 L

Art.-Nr. / Art. No.	Artikelbezeichnung Article description	
225	SW 192 A	10 L
7992	SW 192 A Baxter	6 L
7301	SW 194 A	6 L
3254	SW 194 A	10 L
7994	SW 194 A Baxter	6 L
131	SW 195 A	10 L
88	SW 195 A	300 L
8275	SW 195 A	500 L
8481	SW 195 A	6 L
7210888	SW 196 A	5 L
7825	SW 196 A	5 L
3273	SW 196 A	10 L
3251	SW 196 A	6 L
7800	SW 197 A	6 L
3253	SW 197 A	10 L
3287	SW 206 A	10 L
6834	SW 206 A	300 L
3295	SW 213 A	8 L
7826	SW 215 A	5 L
7544	SW 215 A	10 L
7344	SW 215 A	300 L
7547	SW 215 A	6 L
7729	SW 219 A	6 L
7537	SW 219 A	10 L
7413	SW 219 A	300 L
7709	SW 221 A	10 L
3309	SW 221 A	800 L
7798	SW 222 A	6 L
7710	SW 222 A	10 L
3310	SW 222 A	800 L
352	SW 223 A	10 L
3426	SW 223 A	300 L
129	SW 226 A	500 L
3321	SW 226 A	800 L
218	SW 229 A	8 L
7838	SW 230 A	5 L
3424	SW 230 A	6 L
239	SW 230 A	300 L
224	SW 230 A	800 L
223	SW 230 A	10 L
295	SW 230 A-F	10 L
221	SW 231 A	6 L
214	SW 231 A	800 L
226	SW 231 A	10 L
240	SW 231 A	300 L
296	SW 231 A-F	10 L
159	SW 232 A	8 L
244	SW 232 A	800 L
3210	SW 236 A	10 L
3326	SW 238 A	10 L
7594	SW 239 A	10 L
3333	SW 240 A	6 L
7508	SW 240 A	10 L
3331	SW 240 A	800 L

Art.-Nr. / Art. No.	Artikelbezeichnung Article description	
124	SW 241 A	10 L
3338	SW 243 A	10 L
7417	SW 243 A	300 L
7967	SW 243 A	800 L
7546	SW 245 A	10 L
3343	SW 247 A	10 L
3399	SW 247 A	300 L
3341	SW 247 A	800 L
6827	SW 248 A	6 l
3342	SW 248 A	10 L
6829	SW 248 A	300 l
3397	SW 248 A	800 L
7306	SW 251 A	6 L
7794	SW 251 A	10 L
7801	SW 252 A	6 L
194	SW 252 A	10 L
3351	SW 254 A	10 L
540	SW 254 A	300 L
206	SW 256 A	300 L
7944	SW 258 A	6 L
208	SW 258 A	10 L
7945	SW 258 A	800L
3293	SW 261 A	800 L
7827	SW 262 A	5 L
136	SW 262 A	10 L
7962	SW 262 A	8 L
7377	SW 262 A	300 L
7827	SW 262 A	5 L
7777	SW 262 A	6 L
366	SW 262 A	800 l
301	SW 264 A	10 L
3423	SW 264 A	300 L
112	SW 268 A	10 L
7300	SW 272 A	6 L
8421	SW 272 A	10 L
7972	SW 272 A Baxter	6 L
258	SW 274 A	10 L
7407	SW 274 A	300 L
250	SW 274 A	800 L
7974	SW 275 A	6 l
254	SW 275 A	10 L
251	SW 275 A	800 L
8490	SW 276 A	6 L
7622	SW 276 A	10 L
119	SW 277 A	800 L
8469	SW 278 A	6 L
8491	SW 278 A	10 L
117	SW 284 A	10 l
7782	SW 285 A	6 l
116	SW 285 A	10 l
96	SW 285 A	300 l
98	SW 285 A	500 l
3322	SW 285 A	800 l
7975	SW 286 A	6 l

Art.-Nr. / Art. No.	Artikelbezeichnung Article description	
118	SW 286 A	10 l
93	SW 286 A	300 l
8232	SW 286 A	800 l
3395	SW 294 A	10 l
7995	SW 295 A	6 l
7996	SW 296 A	6 l
7958	SW 296 A	6 L (5 L F.)
7997	SW 297 A	6 l
7998	SW 298 A	6 l
7999	SW 299 A	6 l
7957	SW 299 A	6 L (5 L F.)
7707	SW 307 A	6 L
7509	SW 309 A	10 L
7513	SW 316 A	10 L
7519	SW 319 A	10 L
7908	HDY 320 A HELP	6 L
7565	SW 365 A	10 L
7566	SW 366 A	10 L
7366	SW 366 A	300 L
7266	SW 366 A	500 L
7828	SW 375 A	5 L
7575	SW 375 A	10 L
89	SW 375 A	300 L
7275	SW 375 A	500 L
7579	SW 375 A	800 L
7775	SW 375 A	6 L
7829	SW 376 A	5 L
7576	SW 376 A	10 L
87	SW 376 A	300 L
7276	SW 376 A	500 L
39	SW 376 A	800 L
7776	SW 376 A	6 L
7955	SW 376 A	6 L (5 L F.)
7976	SW 376 A Baxter	6 L
7210885	SW 380 A	5 L
7210766	SW 380 A	5,5 L Bag
7830	SW 380 A	5 L
7830	SW 380 A	5 L
7580	SW 380 A	10 L
7380	SW 380 A	300 L
7280	SW 380 A	500 L
7780	SW 380 A	6 L
7980	SW 380 A Baxter	6 L
7182	SW 380 A	800 L
7210889	SW 381 A	5 L
7210767	SW 381 A	5,5 L Bag
7581	SW 381 A	10 L
7381	SW 381 A	300 L
7281	SW 381 A	500 L
7781	SW 381 A	6 L
7956	SW 381 A	6 L (5 L F.)
7181	SW 381 A	800 L
7589	SW 389 A	10 L
7954	SW 390 A	5 L

Art.-Nr. / Art. No.	Artikelbezeichnung Article description
7590	SW 390 A 10 L
7593	SW 393 A 10 L
7393	SW 393 A 300 L
7293	SW 393 A 500 L
7298	SW 393 A 800 L
7793	SW 393 A 6 L
7379	SW 397 A 6 L
7597	SW 397 A 10 L
7399	SW 397 A 300 L
7297	SW 397 A 500 L
86	SW 397 A 800 L
7398	SW 398 A 300 L
7942	SW 402 A 6 L
7611	SW 402 A 10 L
7943	SW 403 A 6 L
7569	SW 405 A 10 l
7403	SW 406 A 300 L
7602	SW 406 A 800 L
7600	SW 407 A 800 l
7584	SW 408 A 6 l
7570	SW 408 A 10 l
7582	SW 408 A 800 l
7510	SW 409 A 10 l
7601	SW 409 A 800 l
7571	SW 410 A 6 l
7573	SW 413 A 10 L
7592	SW 414 A 10 L
7432	SW 414 A 800 L
7299	SW 415 A 6 L
7302	SW 416 A 10 L
6807	SW 417 A 6 l
7936	SW 417 A 10 L
7400	SW 417 A 500 L
7969	SW 418 A 10 L
7964	SW 419 A 6 L
7970	SW 420 A 6 L
7948	SW 421 A 6 L
7947	SW 422 A 6 L
6805	SW 423 A 6 l
7985	SW 423 A 10 L
6830	SW 423 A 300 l
7402	SW 423 A 500 l
7986	SW 423 A 800 L
7973	SW 424 A 6 l
7987	SW 424 A 10 l
7419	SW 424 A 800 L
6806	SW 425 A 6 l
7988	SW 425 A 10 L
3223	SW 426 A 800 L
3400	SW 427 A 10 L
7797	SW 430 A 6 L
7304	SW 430 A 10 L
7210883	SW 431 A 5 L
7305	SW 431 A 6 L

Art.-Nr. / Art. No.	Artikelbezeichnung Article description
7635	SW 432 A 6 L
7609	SW 433 A 6 L
6808	SW 434 A 6 l
6828	SW 434 A 10 l
6831	SW 434 A 300 l
6832	SW 434 A 500
6833	SW 434 A 800 l
6809	SW 435 A 6 l
7732	SW 436 A 6 L
368	SW 436 A 10 l
7433	SW 436 A 300 L
7428	SW 436 A 500 L
7785	SW 437 A 10 l
7795	SW 438 A 6 L
7796	SW 439 A 6 L
7548	SW 439 A 10 L
3216	SW 440 A 800 L
7971	SW 441 A 6 l
7531	SW 441 A 10 l
7715	SW 442 A 6 l
7425	SW 442 A 300 l
7404	SW 442 A 500 l
7530	SW 443 A 10 l
7728	SW 444 A 6 L
7532	SW 444 A 10 l
7429	SW 444 A 800 L
7733	SW 445 A 6 L
7534	SW 445 A 10 l
7408	SW 445 A 300 L
7410	SW 445 A 500 L
7725	SW 446 A 6 l
7535	SW 446 A 10 l
7409	SW 446 A 300 L
7405	SW 446 A 500 l
7427	SW 446 A 800 L
7799	SW 447 A 6 l
7734	SW 448 A 6 L
7538	SW 448 A 10 L
7426	SW 448 A 300 L
7411	SW 448 A 500 L
7726	SW 449 A 6 l
7541	SW 449 A 10 l
7412	SW 449 A 300 l
7406	SW 449 A 500 l
7542	SW 450 A 10 l
7414	SW 450 A 300 L
7727	SW 451 A 6 l
7543	SW 451 A 10 l
6835	SW 451 A 300 L
7645	SW 452 A 10 L
7598	SW 453 A 10 L
7420	SW 454 A 800 L
7421	SW 455 A 800 L
7422	SW 456 A 500 L

Art.-Nr. / Art. No.	Artikelbezeichnung Article description
7423	SW 457 A 500 L
7424	SW 458 A 500 L
7705	SW 460 A 10 l
7706	SW 461 A 10 l
7210820	SW 462 A 4,7 L Bag
7210846	SW 462 A 4,7 L Canister
7210821	SW 463 A 4,7 L Bag
7210847	SW 463 A 4,7 L Canister
7210822	SW 464 A 4,7 L Bag
7210848	SW 464 A 4,7 L Canister
7210823	SW 465 A 4,7 L Bag
7210849	SW 465 A 4,7 L Canister
7210802	SW 466 A 4,7 L Bag
7210850	SW 466 A 4,7 L Canister
7210824	SW 467 A 4,7 L Bag
7210851	SW 467 A 4,7 L Canister
8496	SW 470 A 10 L
8497	SW 471 A 10 L
8471	SW 472 A 6 L
8498	SW 472 A 10 L
8501	SW 476 A 10 L
7434	SW 478 A 6 L
7210772	SW 501 A 5,5 L Bag
7629	SW 501 A 6 L
7610	SW 501 A 10 L
7639	SW 515 A 10 L
7612	SW 525 A 10 L
7641	SW 526 A 10 L
7613	SW 533 A 10 L
7735	SW 552 A 6 L
7614	SW 552 A 10 L
7642	SW 567 A 10 L
7615	SW 575 A 10 L
7643	SW 577 A 10 L
7616	SW 601 A 10 L
7786	SW 603 A 6 L
7638	SW 603 A 10 L
7617	SW 640 A 10 L
7618	SW 642 A 10 L
7619	SW 649 A 10 L
7620	SW 650 A 10 L
7621	SW 651 A 10 L
7623	SW 704 A 10 L
7624	SW 720 A 10 L
7978	SW 721 A 6 L
7625	SW 721 A 10 L
7626	SW 722 A 10 L
7210890	SW 723 A 5 L
7736	SW 723 A 6 L
7627	SW 723 A 10 L
7418	SW 723 A 300 L
7738	SW 724 A 6 L
7628	SW 724 A 10 L
7630	SW 725 A 6 L

Art.-Nr. / Art. No.	Artikelbezeichnung Article description	
7631	SW 725 A	10 L
7632	SW 726 A	6 L
7644	SW 726 A	10 L
7633	SW 727 A	10 L
7737	SW 728 A	6 L
7634	SW 729 A	10 L
7210762	SW 730 A	5,5 L bag
7803	SW 731 A	6 L
133BBC	SW178A	6 L canister
3269BBC	SW93A	6 L canister
7724BBC	SW139A	6 L canister
7778BBC	SW127A	6 L canister
7780BBC	SW380A	6 L canister
7781BBC	SW381A	6 L canister
7210837	SW 95 A	5,5 L bag
7210854	SW 468 A	4,7 L bag
7210838	SW 469 A	5,5 L Bag
7210870	SW 475 A	4,7 L bag
7210871	SW 475 A	4,7 L Canister
7210853	SW 473 A	4,7 L Canister
7210839	SW 721 A	5,5 L bag
7210840	SW 726 A	5,5 L bag

Additives for Acidic Bic HD Concentrates Class IIb

341	Calciumchlorid 12,9%	100 ml
354	Calciumchlorid 25,7%	100 ml
230	Kaliumchlorid 26,1%	78 ml
232	Kaliumchlorid 26,1%	60 ml
231	Kaliumchlorid 26,1%	100 ml
4250	Soluz.cl.potas. 26,1% 20x60ml	60 ml

Accessories for HD concentrates Class I sterile

7210768	Connection Set for Baxter (EO)
7210769	Connection Set for Gambro (EO)
7210770	Connection Set for Dialog (EO)
7210783	Connector for acidic concentrate bags on Dialog
7210836	Connector for acid concentrates in bag
PP001898	Adapter for acidic concentrates

Wir

We

**B. Braun Medizintechnologie GmbH
Schwarzenberger Weg 73-79
34212 Melsungen
Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**Sol-Cart B®
Natriumhydrogencarbonat für die Hämodialyse**
(Artikelnummern siehe Anlage I)mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen:Richtlinie 93/42/EWG des Rates vom
14. Juni 1993 über Medizinprodukte**Konformitätsbewertungsverfahren:**
nach Anhang II Absatz 3
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der oben genannten Richtlinie:

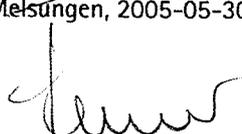
Klasse IIb, Regel 3

EG-Zertifikat Nr.
G1 05 01 21273 011**Benannte Stelle:**
TÜV Product Service GmbH
Kennnummer 0123**Datum der ersten CE-Kennzeichnung:**
1998-09hereby declare in our own responsibility
that the product/s**Sol-Cart B®
Sodium bicarbonate for haemodialysis**
(article numbers see attachment I)

is/are in compliance with the following directive:

Council Directive 93/42/EEC of 14 June 1993
concerning medical devices**Conformity assessment procedure:**
according to annex II clause 3
of the Directive named above**Classification**
according to annex IX of the Directive named
above:
Class IIb, Rule 3**EC Certificate No.**
G1 05 01 21273 011**Notified body:**
TÜV Product Service GmbH
Identification number 0123**Date of first CE-marking:**
1998-09

Melsungen, 2005-05-30

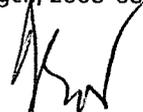

Dr. Wolfgang Feller
Managing Director

Mirandola, 2005-05-30


Dr. Giuliana Gavioli
Head of Division RA

Melsungen, 2005-05-30

i. V.


Birgit Unger
Head of Division QM

Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Kartuschen pro Box / Cartridges per Box
494	Sol-Cart B® 760 g	10 x 760 g
496	Sol-Cart B® 650 g	10 x 650 g
499	Sol-Cart B® 650 g	10 x 650 g
501	Sol-Cart B® 760 g	10 x 760 g
512	Sol-Cart B® 760 g	10 x 760 g
507	Sol-Cart B® 650 g	32 x 650 g
515	Sol-Cart B® 760 g	32 x 760 g
518	Sol-Cart B® 650 g	40 x 650 g
519	Sol-Cart B® 760 g	40 x 760 g



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 03 66097 061

Manufacturer: **B. Braun Avitum AG**
Schwarzenberger Weg 73 - 79
34212 Melsungen
GERMANY

Facility(ies): B. Braun Medical AG
Seesatz 17, 6204 Sempach, SWITZERLAND

B. Braun Avitum AG, Werk Glandorf
Kattenvenner Straße 32, 49219 Glandorf, GERMANY

Product Category(ies): **Disinfectants for Dialysis Machines**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713036667

Valid from: 2014-05-18
Valid until: 2019-05-17

Date, 2014-04-02

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1

EC SERTIFIKATAS

Kokybės užtikrinimo sistema

(Medicinos priemonių 93/42/EEC direktyvos II priedas, išskyrus (4)
(Priemonės IIa, IIb ar III)

Nr.: G1 14 03 66097 061

Gamintojas: **B.Braun Avitum AG**
Schwarzenberger Weg 73-79
34212 Melsungen
Vokietija

Gamykla (-os): B.Braun Medical AG
Seesatz, 6203 Sempach-Station, Šveicarija

B.Braun Avitum AG, Werk Glandorf
Kattenvenner Str.32, 49219 Glandorf, Vokietija

Produkto **Dezinfektantai dializės aparatams**
 kategorija (-jos)

TUV Product Service GmbH sertifikavimo įstaiga patvirtina, kad nurodytas gamintojas įdiegė Direktyvos MDD dėl medicinos įrenginių II priedo numatytų gaminių ir jų kategorijų kūrimo, gamybos ir galutinio patikrinimo kokybės užtikrinimo sistemą. Ši kokybės užtikrinimo sistema atitinka šios Direktyvos nuostatas ir yra nuolat stebima. Norint platinti III klasės gaminius būtina gauti papildomą II.4 priede numatytą sertifikatą. Taip pat žr.pastabas kitoje lapo pusėje.

Pranešimo Nr.: 713036667

Galioja nuo: 2014 05 18

Galioja iki: 2019 05 17

Data 2014 04 02 */Parašas/*
Hans-Heiner Junker

TÜV PRODUCT SERVICE GMBH yra oficiali tarnyba, Identifikacijos Nr. 0123.
Puslapis 1 iš 1

TÜV PRODUCT SERVICE GMBH, Sertifikavimo tarnyba, Ridlerstrasse 65, D-80339 Miunchenas

CE - Declaration of Conformity

We

B. Braun Medizintechnologie GmbH
Schwarzenberger Weg 73-79
D - 34212 Melsungen

Production Site

B. Braun Medizintechnologie Site Glandorf
Kattenvenner Straße 32
D - 49219 Glandorf

declare in our own responsibility, that the product/s

**Liquid Concentrate for the cleaning, decalcification and heat disinfection of
haemodialysis machines (class IIa)**

Citric Acid 50 %, 6 l canister, REF **889** with date of first production **2003-05-15**
and

Citric Acid 50 %, 10 l canister, REF **307** with date of first production **2003-05-15**

Is/are in compliance with the following directive:

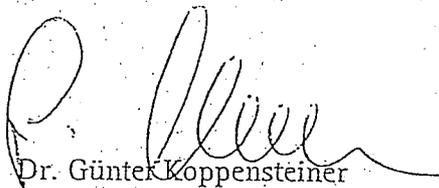
Council Directive 93/42/EEC
of 14 June 1993
concerning Medical Devices

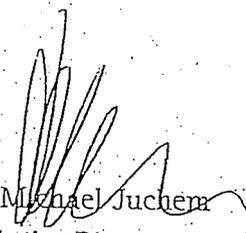
Product/s is/are covered by CE Certificate No. G1 03 05 21273 027 issued by:

TÜV PRODUCT SERVICE GMBH

as notified body according to Council Directive 93/42/EEC concerning
medical devices with identification no. 0123

Melsungen, 2003-05-12


Dr. Günter Koppensteiner
Quality and Regulatory Affairs Manager


Dr. Michael Juchem
Marketing Director

ATITIKTIES DEKLARACIJA

Mes

B.Braun Medizintechnologie GmbH,
Schwarzenberger Weg 73-79,
D-34212 Melsungen

Produkcijos vieta:

B.Braun Medizintechnologie GmbH Glandorf
Kattenvenner Str.32
D-49219 Glandorf

prisiimdami atsakomybę, pareiškiame, kad šis produktas/-ai

Skystas koncentratas hemodializės aparatų plovimui, dekalcinavimui ir dezinfekcijai (II a klasė)

Citrinos rūgštis 50%, 6 l talpos, REF 889 , produkcijos pradžia 2003 05 15
ir

Citrinos rūgštis 50%, 10 l talpos, REF 307, produkcijos pradžia 2003 05 15

kuriam/-iems taikoma ši deklaracija, atitinka sekančią direktyvą

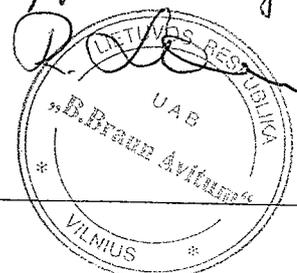
93/42/EEC Tarybos direktyva
1993 m. birželio 14 d.
apie medicinos priemonės

Produktas/-ai yra apsaugotas CE Sertifikatu Nr. G1 03 05 21273 027, kuris išduotas:
TÜV PRODUCT SERVICE-
oficialios tarnybos, veikiančios pagal tarybos medicininės įrangos direktyvą 93/42/EEC.
Identifikacijos Nr. 0123.

Melsungen, 2003 05 12

/parašas/
Dr.Martin Renken

Teksta:
Deklaracija komercijai ir
neesteticinai
Demetrius Kozgalevs



EC Declaration of Conformity

We

B. Braun Medizintechnologie GmbH
Schwarzenberger Weg 73-79
34212 Melsungen
GERMANY

Production Site:
B. Braun Medical AG
Seesatz
6203 Sempach-Station
SWITZERLAND

declare in our own responsibility, that the product

Tiutol® KF, 5 l canister, Article number 7120222
Disinfectant for haemodialysis monitors and instruments

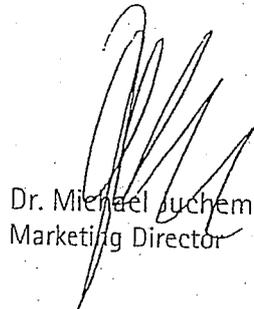
which is covered by this declaration is in compliance with the following directives/ standards

Council Directive 93/42/EEC
of 14 June 1993
concerning Medical Devices

Reference: EC Certificate No. G1 03 05 21273 027

Melsungen, 2003-05-12


Dr. Günter Koppensteiner
Quality and Regulatory Affairs Manager


Dr. Michael Juchem
Marketing Director

EB ATITIKTIES DEKLARACIJA

Mes

**B.Braun Medizintechnologie GmbH,
Schwarzenberger Weg 73-79,
D-34212 Melsungen
VOKIETIJA**

Produkcijos vieta:
B.Braun Medical AG
Seesatz
6203 Sempach-Station
ŠVEICARIJA

prisiimdami atsakomybę pareiškiame, kad šis produktas

Tiutol KF, 5 l talpos, Art.Nr.7120222
Dezinfekcijos priemonė, skirta hemodializės monitoriams ir instrumentams

kuriam taikoma ši deklaracija, atitinka sekančias direktyvas/ standartus:

93/42/EEC Tarybos direktyva
1993 m. birželio 14 d.
apie medicinos priemones

Nuoroda: EB sertifikatas Nr. G1 03 05 21273 027

Melsungenas, 2003 05 12

/parašas/
Dr. Giunter Koopensteiner
(Kokybės ir registracijos sk.
vadybininkas)

Tikras:
Dr. Michael Juchem
komercijai ir
medicinai
darbuotojas

/parašas/
Dr. Michael Juchem
(Marketingo sk. vadovas)

