# MDD Declaration of Conformity (Form)



Wir | We

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

erklären in eigener Verantwortung,
dass das/die Produkt/e
**Kit für Dialyse und Haemo(dia)filtration**
(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 mit Ausnahme der nummer (4)
der oben genannten Richtlinie
**Klassifizierung**
gemäß Anhang IX der oben genannten Richtlinie:
Klasse IIb, Regel 3
**EG-Zertifikat Nr.**
G1 066097 0096 Rev. 02

**Konformitätsbewertungsverfahren:**
nach Anhang V und Anhang VII
der oben genannten Richtlinie
**Klassifizierung**
gemäß Anhang IX der oben genannten Richtlinie:
Klasse I Sterile, Regel 1
**EG-Zertifikat Nr.**
G2S 17 08 66097 082
**Benannte Stelle:**
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Deutschland
Kennnummer 0123

**Datum der ersten CE-Kennzeichnung:**
2015-01

Doc #: 02/15-RA-fo
Doc Rev #: 11.0
Rev date: 2020-03-04

**Gültigkeit dieser Erklärung:**
von 2020-03-09
bis 2023-01-09

Radeberg, 2020/03/09

Anton Deisser
**Head of CoE Fluids, Concentrates and Disposables**

hereby declare in our own responsibility
that the product/s
**Kit for Dialysis and Haemo(dia)filtration**
(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 excluding (4)
of the Directive named above
**Classification**
according to annex IX of the Directive named above:
Class IIb, Rule 3
**EC Certificate No.**
G1 066097 0096 Rev. 02

**Conformity assessment procedure:**
according to Annex V and Annex VII
of the Directive named above
**Classification**
according to annex IX of the Directive named above:
Class I Sterile, Rule 1
**EC Certificate No.**
G2S 17 08 66097 082
**Notified body:**
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
Identification number 0123

**Date of first CE-marking:**
2015-01

Doc #: 02/15-RA-fo
Doc Rev #: 11.0
Rev date: 2020-03-04

**Validity of this declaration:**
from 2020-03-09
until 2023-01-09

Mirandola, 09.03.20

Dr. Giuliana Gavioli
**Head of Division RA**

## Anlage I / Attachment I

| Art. No. | Description | Class | Rule |
|---|---|---|---|
| 7211136 | OMNIset Including 0.8 sqm Hemofilter | IIb | 3 |
| 7211137 | OMNIset Including 1.2 sqm Hemofilter | IIb | 3 |
| 7211151 | OMNIset Including 1.6 sqm Hemofilter | IIb | 3 |
| 7211265 | OMNIset Plus Including 1.6 sqm Hemofilter | IIb | 3 |
| 7211427 | OMNIset® Plus | IIb | 3 |
| 7211432 | OMNIset® ECCO$_2$R | IIb | 3 |
| 7211287 | OMNIset PRO Including 1.3 sqm Hemofilter | IIb | 3 |
| 7211288 | OMNIset PRO Including 1.6 sqm Hemofilter | IIb | 3 |
| 7211367 | OMNIset® L 1.6 m² | IIb | 3 |
| 7211368 | OMNIset® 0.8 m² | IIb | 3 |
| 7211369 | OMNIset® 1.2 m² | IIb | 3 |
| 7211370 | OMNIset® 1.6 m² | IIb | 3 |
| 7211371 | OMNIset® Pro 0.8 m² | IIb | 3 |
| 7211372 | OMNIset® Pro 1.2 m² | IIb | 3 |
| 7211373 | OMNIset® Pro 1.6 m² | IIb | 3 |
| 7211422 | OMNIset® 1.3 m² | IIb | 3 |
| 7211423 | OMNIset® 1.6 m² | IIb | 3 |
| 7211428 | OMNIset® 1.3 m² | IIb | 3 |
| 7211429 | OMNIset® 1.6 m² | IIb | 3 |
| 7211425 | OMNIset® Pro 1.3 m² | IIb | 3 |
| 7211426 | OMNIset® Pro 1.6 m² | IIb | 3 |
| 7211376 | OMNIset® Pro 1.3m² | IIb | 3 |
| 7211377 | OMNIset® Pro 1.6 m² | IIb | 3 |
| 7211065 | OMNIbag 7000 mL Effluent bag | I sterile | 1 |

Radeberg, 2020/03/09

Anton Deisser
**Head of CoE Fluids, Concentrates and Disposables**

Mirandola, 10.03.05

Dr. Giuliana Gavioli
**Head of Division RA**

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

# EC Certificate

## Production Quality Assurance System

**Directive 93/42/EEC on Medical Devices (MDD), Annex V**
**(Devices in class I in sterile conditions, sterilised systems or procedure packs)**

**No. G2S 17 08 66097 082**

**Manufacturer:**

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

**Facility(ies):**

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

**Product Category(ies):**

**Accessories for dialysis, infusion and apheresis (class I sterile)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** 713113517

**Valid from:** 2018-01-10
**Valid until:** 2023-01-09

**Date,** 2017-10-11

Stefan Preiß

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





TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Certificat CE

Sistem complet de asigurare a calității
Directiva 93/42/EEC privind dispozitivele medicale (MDD), anexa II, cu excepția secțiunii (4)
(Dispozitive aparținând clasei I în condiții sterile, sisteme sterilizate sau pachete de proceduri)

Nr. G2S 17 08 66097 082

| | |
|---|---|
| Producător: | B. Braun Avitum AG<br>Schwarzenberger Weg 73 – 79<br>34212 Melsungen<br>GERMANIA |
| Sedii: | B. Braun Avitum Italy S.p.A.<br>Via XXV Luglio, 11, 41037 Mirandola (MO), ITALIA |
| Categorie (categorii) produse: | Accesorii pentru dializă, infuzie și afereză<br>(clasa I, sterile) |

Organismul de certificare TUV SUD Product Service GmbG atestă că producătorul menționat mai sus a implementat un sistem de asigurare a calității pentru proiectarea, fabricarea și inspecția finală a dispozitivelor în cauză / categoriilor de dispozitive, în conformitate cu directiva privind dispozitivele medicale, anexa II. Sistemul de asigurare a calității este în conformitate cu cerințele directivei și este supus unei supravegheri periodice. Pentru comercializarea dispozitivelor aparținând clasei III, este necesar un certificat suplimentar conform anexei II (4). Vezi notele de pe verso.

Nr. raport: 713113517

Valabil de la: 2018-01-10
Valabil până la: 2023-01-09


Data, 2017-10-11

[semnătură indescifrabilă]
Stefan Preiß

TUV SUD Product Service GmbH este un organism notificat cu numărul de identificare 0123.