



# उत्तर प्रदेश आयुर्विज्ञान विश्वविद्यालय

सैफई, इटावा (उ०प्र०)

Uttar Pradesh University of Medical Sciences

Saifai, Etawah - 206 130 (U.P.)

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पत्र संख्या- 418/U.P.U.M.S./2192/MM-Medicine/26-27

दिनांक 28-Sep-2026

## सूचना

"सर्वसाधारण को अवगत कराना है कि इस विश्वविद्यालय के मेडिसिन विभाग में स्थापित उपकरण Dialysis Machine (M/s B- Braun Medical India Pvt Ltd) में प्रयोग होने वाले सामग्री Diacap Ultra DF Online filter & Tricarb C 50 (Disinfectant) की अवयवशक्ता को दर्शाया गया है जो निम्न है

| S.No | Dialysis Machine (M/s B- Braun Medical India Pvt Ltd) | OEM                  |
|------|-------------------------------------------------------|----------------------|
| 1    | Diacap Ultra DF Online filter                         | M/s B- Braun Medical |
| 2    | Tricarb C 50 (Disinfectant)                           | M/s B- Braun Medical |

उपरोक्त तालिका में प्रदर्शित सामग्री हेतु ओ०ई०एम० फर्म M/s B- Braun Medical द्वारा अपने प्रोपराइटी सर्टिफिकेट को प्रस्तुत करते हुए घोषित किया है कि उक्त सामग्री उनका प्रोपराइटी प्रोडक्ट है।

अतः उपरोक्त तालिका में प्रदर्शित ओ०ई०एम० फर्म की इस घोषणा के संबंध में किसी व्यक्ति/ फर्म / निर्माता को कोई आपत्ति है तो वह इस सूचना के अपलोड होने की तिथि से 05 (Five) दिवसों के अन्दर अपनी आपत्ति ई-मेल आई०डी०rimsmmdept@gmail.com पर प्रेषित कर सकता है। उक्त अवधि के उपरांत उक्त प्रकरण से सम्बन्धित किसी भी आपत्ति पर विचार नहीं किया जायेगा।"

*HP*

(डा० हिमांशु प्रिंस)

इचार्ज प्रोक्योरमेंट

(उपकरण विभाग-विशिष्ट)

प्रतिलिपि:- निम्नलिखित को सूचनार्थ प्रेषित-

1. प्रभारी सी०ए०सी० को उक्त सूचना एवम् संबंधित पी०ए०सी० सर्टिफिकेट विश्वविद्यालय की वेबसाइट पर प्रकाशित करने हेतु।

website

29/9/26

B | BRAUN

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

Date: October 13, 2025

TO WHOM IT MAY CONCERN

PROPRIETARY ARTICLE CERTIFICATE (PAC)

Product: DF-ONLINE FILTER  
Brand Name: DIACAP ULTRA  
Manufacturer: B. Braun Avitum AG  
Schwarzenberger Weg 73-79,  
34212, Melsungen, Germany  
Phone: +49 5661710  
Email: regulatoryaffairs\_ba.it@bbraun.com  
Manufacturing Site: B. Braun Avitum Saxonia GmbH  
Juri-Gahgarin Strasse 13  
01454 Radeberg, Germany  
Phone: +49 35284190  
Email: regulatoryaffairs\_ba.it@bbraun.com

Intended Use:

Indication

Diacap Ultra Dialysis Fluid Filter is a bacterial and pyrogen filter and is used to produce highly pure dialysis fluid and to prepare replacement solution for online HDF and HF procedures during the treatment.

Precautionary measures on application

- Storage up to the given expiry date : between 0°C and 30°C.
- Ensure that no chemicals , oil- containing products and other harmful substances are in the vicinity.
- Please read the operating instructions before using the filter.
- Do not use the product after the expiry date. The expiry date applies only for the correctly stored product with undamaged packaging.
- The filter must not be used if you discover damage to the packaging or filter.
- The sterility of the product is guaranteed only if the packaging is undamaged. To guarantee sterility , use the filter immediately after taking it from its packaging.

Chairman of the Supervisory Board:  
PD Dr. Stefan Hoppert

Executive Board:  
Dr. Jean-Claude Dubacher  
(Chief Executive Officer)  
Dr. Hilger Seelberg  
Andreas Wölke

Corporate Offices: Melsungen  
Register Court: Local Court Fittlar  
HRB 11 283  
VAT reg.no. DE210562570  
WEEE-reg.-no. DE 95621303

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

*Dr. Manoj Kumar*  
**Dr. Manoj Kumar**  
M.D Medicine  
Prof & HOD  
Department of Medicine  
UPUMS, Saurat Erawan 206130

**Description of the product**

Diacap® Ultra Dialysis Fluid Filter is a bacterial and pyrogen filter and is used to produce highly pure dialysis fluid and to prepare replacement solution for online HDF and HF procedures during the treatment. The filter can be used for a variety of purposes in Dialog dialysis equipment manufactured by B. Braun. These options include use as "pyrogen filter" in chronic haemodialysis, haemofiltrations, and haemodiafiltration treatment and "online" in haemofiltration and haemofiltration treatment. Use as a dialysis fluid filter is indicated. Use as a filter for the purification of dialysis fluid in other dialysis equipment must be coordinated with B. Braun. In addition, the chemical and microbiological composition of the water employed and of the concentrate must meet the stipulations of the European Pharmacopoeia for "Purified water" (aqua purificata) and current standards.

**TECHNICAL DATA**

|                              |                   |
|------------------------------|-------------------|
| Ultrafiltration Coefficient: | 270 ml/h/mmHg     |
| Membrane:                    | Polysulphone      |
| Housing:                     | Polycarbonate     |
| Potting compound:            | Polyurethane      |
| O-ring:                      | Silicon           |
| Endotoxin                    |                   |
| Retention capacity:          | $\geq 10^6$ EU/ml |
| Working life:                | 150 treatments    |
| Connector:                   | Hansen connector  |
| Max. filter pressure:        | 2 bar             |
| Max. TMP:                    | 500 mmHg          |

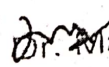
TMP= Transmembrane Pressure

Table 1- Diacap Ultra Technical Data

The device is individually packed in a transparent flexible peel pouch and single cardboard boxes. Six cardboard boxes are packed in one covering box. Storage temperature : between 0°C and 30°C.

Diacap Ultra are Class IIa medical device according to Annex IX of MDD 93/42/EEC, Rule 3. "All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of

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Andreas WaldeCorporate Office: Melsungen  
Register Court: Local Court Fritzlar  
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34212 Melsungen

filtration, centrifugation or exchanges of gas heat, in which case they are in Class IIa."

The medical device nomenclature is as follows:

GMDN: Haemodialysis system dialysate pyrogen filter - code 47739

UMDN code: water purification filter- code 15611

Method of sterilization for Diacap Ultra devices: Gamma-Radiation

Diacap Ultra must not be re-sterilized and have a shelf life of 3 years.

This is a proprietary item manufactured by B Braun Avitum AG, Germany and marketed through B Braun Medical (India) Pvt. Ltd. who is marketing authorization holder in India.

B. Braun Avitum AG

i. V.

*Chiara Bergamini*  
Chiara Bergamini  
VP Regulatory Affairs

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i. A.

*Francesca Tintori*  
Francesca Tintori  
RA Renal Team Leader - HD Chronic

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TO WHOM IT MAY CONCERN

B. Braun Medical Industries Sdn. Bhd.  
(Company Reg: 197401001922 (19051-M))

Bayan Lepas Free Industrial Zone  
11900 Pulau Pinang, Malaysia

Tel : 604-6333100  
Fax : 604-6433750  
www.bbraun.com.my

23 April 2024

RE: PROPRIETARY ARTICLE CERTIFICATE (P.A.C)

We, hereby certify that

B. Braun Medical Industries Sdn. Bhd.  
Bayan Lepas Free Industrial Zone  
11900 Bayan Lepas.  
Penang, Malaysia

is the sole manufacturing facility of Tricarb C-50, 5L canister (Citric Acid 50%)

Composition:

1000 ml contains 500g citric acid, anhydrous

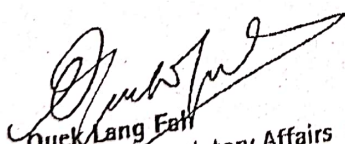
Intended use:

Liquid concentrate for the cleaning, decalcification and heat-disinfection of the fluid pathway of hemodialysis machines

This is a proprietary item manufactured by B. Braun Medical Industries Sdn. Bhd., distributed by B. Braun Medical (India) Pvt. Ltd., the Marketing Authorization Holder in India.

Yours faithfully,

B. Braun Medical Industries Sdn. Bhd.

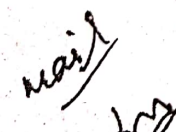
  
Quek Lang Foh  
Director - Regulatory Affairs

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Vignesvaran Subramanian  
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