

**Reporting requirement according to paragraph 33 of the 'REACH' regulation  
(EG No. 1907/2006)**

June 12, 2014

Dear Sir or Madam,

B. Braun Avitum AG confirms with the CE-labelling and with the declaration of conformity of our medical devices that the respective products are in compliance with the "essential requirements" of the European Medical Device Directive (93/42/EEC) dated June 14th, 1993.

This includes that B. Braun Avitum AG medical devices are designed and manufactured in a way that, when used under the conditions and for the purpose intended, they will not compromise the clinical condition or the safety of patients nor the safety and health of users or third parties. This assessment was carried out as part of the B. Braun Avitum AG Risk Management System implemented according to ISO 14971, "Application of Risk Management to Medical Devices".

Since adoption of the European Regulation 'REACH' (Registration, Evaluation and Authorization of Chemicals) we have to inform which devices include a substance named in the so called list of candidates in a concentration of more than 0.1 mass percentage. This list was announced to the public on the 'ECHA' website (European Chemical Agency) on October 28th, 2008 and has been updated continuously.

Concerning substances published in the list of candidates, only DEHP (Bis(2-ethylhexyl) phthalate) is present in relevant concentrations. The following product groups of the B. Braun Avitum AG contain more than 0.1 mass percentage DEHP:

- Bloodline systems for haemodialysis machines, for the acute dialysis machine Diapact CRRT and the H.E.L.P. system
- Fistula needles
- Haemodialysis concentrates and rinsing/priming solutions contained in PVC bags (not applicable to all concentrates and solutions in containers other than PVC bags).

This letter will be updated if a substance relevant to our products is added to the list of candidates. Until then this letter is valid.

For further questions please do not hesitate to contact us.


Yours sincerely,

B. Braun Avitum AG

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Bertram König  
Senior Vice President Regulatory Affairs

i. V.

  
Dr. Bettina Teschner  
Vice President Quality