

# EU DECLARATION OF CONFORMITY

## Fresenius Medical Care AG & Co. KGaA

Else-Kröner-Str. 1  
61352 Bad Homburg – Germany  
SRN: DE-MF-000008193


**declares under his sole responsibility that the product**

Product Name: *Filtrate Bag 10 L*  
GMN / Basic UDI-DI: *4039361-0000-0000-0120-N8*  
Product group: *Acute dialysis drainage sets*  
Intended Purpose: *Collection of waste fluid in an extracorporeal treatment*

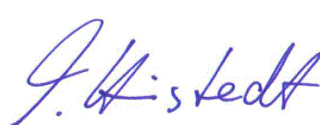
**meets the applicable provisions as stated below and the relevant standards and common specifications as specified in the technical documentation.**

Applicable regulation/s: *European Medical Device Regulation 2017/745*  
Risk class: *Class I according to Rule 1*  
(according to Annex VIII Medical Device Regulation 2017/745)  
Conformity assessment procedure: *Art. 52(7) & Annex IV (Declaration of Conformity) according Regulation (EU) 2017/745 (MDR)*  
Notified body: *Not applicable*  
Notified body no.: *Not applicable*  
EU certificate: *Not applicable*  
Place, Date: *Bad Homburg,*

i.V.

  
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Dr. Rüdiger Amberg  
Product Center Responsible Person

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Dr. Thomas Himstedt  
Responsible person acc. MDR Art. 15

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## Versions:

Product code	Product name
F00007116	Filtrate Bag 10 L

## Accessories:

(according to the European Medical Device Regulation 2017/745)

Product code	Product name
-	-

## Additional equipment:

(Additional equipment which can be used with the respective product, is not covered by this Declaration of Conformity)

Product code	Product name
-	-