

# EU DECLARATION OF CONFORMITY

## Fresenius Medical Care AG

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


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

Product Name: *VenAcc Patch*  
Product Code: *F00003229*  
GMN / Basic UDI-DI: *4039361-0000-0000-0076-PC*  
Product Group: *VenAcc patches*  
EMDN Code: *F9080*  
Intended Purpose: *Detection of disconnection at vascular blood access*

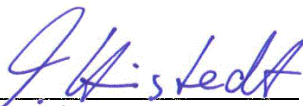
**meets the applicable provisions as stated below and the relevant standards and common specifications as specified in the technical documentation.**

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, 01-Dec-2023*

i.V.

  
\_\_\_\_\_  
Dr. Rüdiger Amberg  
Product Center Responsible Person

ppa

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