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:	*VenAcc Patch*
GMN / Basic UDI-DI:	*4039361-0000-0000-0076-PC*
Product group:	*VenAcc patches*
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: (according to Annex VIII Medical Device Regulation 2017/745)	*Class I according to Rule 1*
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-Dez-2021*

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i.V. Dr. Thomas Wild
Dr. Thomas Wild
Product Center Responsible Person

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

This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.

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Versions:

Product code	Product name
F00003229	VenAcc Patch

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
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