

## ÄNDERUNG / AMENDMENT KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

### *Name und Adresse des Herstellers / Name and address of the manufacturer*

Joline GmbH & Co. KG  
Neue Rottenburger Str. 50  
72379 Hechingen  
Germany

Die aktuell gültige Konformitätserklärung zur Produktfamilie **Dialyse Katheter ST** in der Revision R17 vom 2020-12-04 wird gemäß Artikel 120 Verordnung (EU) 2017/745 geändert. Die Änderungen sind im Anhang (Produktliste) blau markiert. Ferner wird unter Berücksichtigung der Verordnung (EU) 2023/607 die Gültigkeit gemäß dem aktuell vorliegenden Bestätigungsschreiben 50565-CoL-01, Rev.0 der Benannten Stelle verlängert. /

*The currently valid Declaration of Conformity for the product family **Dialysis Catheter ST** in revision R17 dated 2020-12-04 is amended according to Article 120 Regulation (EU) 2017/745. The changes are marked in blue in the annex (product list). Furthermore, taking into account Regulation (EU) 2023/607, the validity is extended in accordance with the current Confirmation Letter 50565-CoL-01, Rev.0 from the Notified Body.*

### *Konformitätsbewertungsverfahren / Conformity assessment procedure*

gemäß Richtlinie 93/42/EWG, Anhang II ohne Abschnitt (4) /  
according to directive 93/42/EEC Annex II without section (4)

### *Konformitätsbewertungsstelle / Notified Body*

DEKRA Certification GmbH  
Handwerkstr. 15  
70565 Stuttgart  
Germany  
ID: 0124

Diese Änderung ist gültig bis zum **31.12.2028** bzw. bis zur Ausstellung einer revidierten Konformitätserklärung. /

*This amendment is valid until **31.12.2028** or until the issuance of a revised Declaration of Conformity.*

Hechingen, 29.11.2023

  
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Michael Eisenlohr  
CEO

  
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Dr. Marian Wenzel  
Director QA/RA

## ANHANG – PRODUKTLISTE / ANNEX – PRODUCT LIST

### Single Lumen Short Term

DCPT 8/15 H-PH	DCPT 8/17,5 H-PH	DCPT 8/20 H-PH	DCPT 8/25 PH
DCPT 8/15 PH	DCPT 8/17,5 PH	DCPT 8/20 PH	

### Double Lumen Short Term Standard

DLS 11/20 C	KDL11P150	KDL11PH250	PKDL11P175C 21
DLS 11/12,5	KDL11P175	PKDL11P125	PKDL11P175R
DLS 11/15	KDL11P200	PKDL11P125R	PKDL11P200
DLS 11/15 C	KDL11P225	PKDL11P150	PKDL11P200R
DLS 11/17,5	KDL11P250	PKDL11P150 21	PKDL11P250
DLS 11/17,5 C	KDL11PH125	PKDL11P150C 21	PKDL11P250R
DLS 11/20	KDL11PH150	PKDL11P150R	
DLS 11/25	KDL11PH175	PKDL11P175	
KDL11P125	KDL11PH200	PKDL11P175 21	

### Double Lumen ST (Händler / Distributor)

-PKDL11P125	-PKDL11P200	-PKDL11P150R	-PKDL11P250R
-PKDL11P150	-PKDL11P250	-PKDL11P175R	
-PKDL11P175	-PKDL11P125R	-PKDL11P200R	

JDC-1115J

JDC-1117,5J

JDC-1120J

### Double Lumen Short Term High Flow

HF-DLS 11/12,5	HF-DLS 11/20	HF-DLS 11/30	PKHF11P200R
HF-DLS 11/12,5 C	HF-DLS 11/20 C	PKHF11P150	PKHF11P250R
HF-DLS 11/15	HF-DLS 11/20 C 14	PKHF11P175	PKHF11P150R 21
HF-DLS 11/15 C	HF-DLS 11/22,5	PKHF11P200	PKHF11P150C 21
HF-DLS 11/15 C 14	HF-DLS 11/25	PKHF11P250	PKHF11P175C 21
HF-DLS 11/17,5	HF-DLS 11/25 C	PKHF11P150R	
HF-DLS 11/17,5 C	HF-DLS 11/25 C 14	PKHF11P175R	
HF-DLS 13/15	HF-DLS 13/20 C	PKHF13PH150C 21	PKHF13PH200R
HF-DLS 13/15 C	HF-DLS 13/25	PKHF13PH150R	PKHF13PH250
HF-DLS 13/17,5	HF-DLS 13/22,5	PKHF13PH175	PKHF13PH250R
HF-DLS 13/17,5 C	PKHF13PH150	PKHF13PH175R	PKHF13PH300
HF-DLS 13/20	PKHF13PH150 21	PKHF13PH200	

## High Flow Double Lumen ST (Händler / Distributor)

-PKHF11P150 -PKHF11P175	-PKHF11P200 -PKHF11P250	-PKHF11P150R -PKHF11P175R	-PKHF11P200R -PKHF11P250R
JHC-1115 JHC-1115J	JHC-1117,5 JHC-1117,5J	JHC-1120 JHC-1120J	JHC-1125
-PKHF13PH150 -PKHF13PH175 -PKHF13PH300	-PKHF13PH200 -PKHF13PH250	-PKHF13PH150R -PKHF13PH175R	-PKHF13PH200R -PKHF13PH250R
JHC-1315 JHC-1315J	JHC-1317,5 JHC-1317,5J	JHC-1320 JHC-1320J	JHC-1325

## Double Lumen Extra Flow – Pädiatrisch /Pediatric

KDL06P100 KDL08P125 P-DLS 6,5/10 P-DLS 6,5/10 C P-DLS 6,5/7,5 P-DLS 6,5/7,5 C P-DLS 6,5/12,5	P-DLS 8/15 P-DLS 8/10 C P-DLS 8/12,5 P-DLS 8/12,5 C P-DLS 8/7,5 P-DLS 8/10 PKDL06P075	PKDL06P075R PKDL06P100 PKDL06P100R PKDL06P125 PKDL06P125R PKDL08P100 PKDL08P100R	PKDL08P125 PKDL08P125R PKDL08P150 PKDL08P150 21 PKDL08P150R
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## Extra Flow Double Lumen (Händler / Distributor)

-PKDL08P100 -PKDL08P125 -PKDL08P150	-PKDL08P100R -PKDL08P125R -PKDL08P150R	-PKDL06P075 -PKDL06P100 -PKDL06P125	-PKDL06P075R -PKDL06P100R -PKDL06P125R
JDC-607,5P JDC-810P	JDC-610P JDC-812,5P	JDC-612,5P JDC-815P	

## Triple Lumen Short Term

TLK 12/15 TLK 12/17,5 TLK 12/20 TLK 12/25 TLK 12/15 C	TLK 12/17,5 C TLK 12/20 C PKTL12P150 PKTL12P150 C 21 PKTL12P150R	PKTL12P175 PKTL12P175 21 PKTL12P175C 21 PKTL12P175R PKTL12P200	PKTL12P200C 21 PKTL12P200 21 PKTL12P200R PKTL12P250R PKTL12P250
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## Triple Lumen ST (Händler)

-PKTL12P150 -PKTL12P175	-PKTL12P200 -PKTL12P250	-PKTL12P150R -PKTL12P175R	-PKTL12P200R -PKTL12P250R
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## Triple Lumen Short Term High Flow

HF-TLK 13/15	HF-TLK 13/25	PKTHF13P150R	PKTHF13P200R
HF-TLK 13/15 C	HF-TLK 13/30	PKTHF13P175	PKTHF13P250
HF-TLK 13/17,5	HF-TLK 13/30 C	PKTHF13P175R	PKTHF13P250R
HF-TLK 13/17,5 C	PKTHF13P150	PKTHF13P175C 21	
HF-TLK 13/20	PKTHF13P150 21	PKTHF13P200	
HF-TLK 13/20 C	PKTHF13P150C 21	PKTHF13P200 21	

## Triple Lumen ST (Händler)

-PKTHF13P150	-PKTHF13P200	-PKTHF13P150R	-PKTHF13P200R
-PKTHF13P175	-PKTHF13P250	-PKTHF13P175R	-PKTHF13P250R
JTC-1315	JTC-1317,5	JTC-1320	
JTC-1315J	JTC-1317,5J	JTC-1320J	