

## Declaration of Conformity

We, Serumwerk Bernburg Vertriebs GmbH, herewith declare under sole responsibility conformity of the medical device

### Sterile Tubing Sets for Hemodialysis and Disposables

with Council Directive 93/42/EEC of June 1993 concerning medical devices.

The conformity assessment procedure has been performed according to Annex II – excluding section 4 of the Council Directive 93/42/EEC.

This declaration of conformity is valid until: 26.05.2024

**Certificate Registration no.:** D1082900028

**Classification acc. Annex IX of 93/42/EEC:** Class IIa, Rule 2

**Notified body:** mdc, CE 0483  
medical device certification GmbH  
Kriegerstraße 6  
D-70191 Stuttgart

Bernburg, 25.05.2021

Serumwerk Bernburg Vertriebs GmbH

A handwritten signature in blue ink, appearing to read 'Zinner', written over a horizontal line.

Bernhard Zinner  
-Managing Director-

## Annex to Declaration of Conformity

### Sterile Tubing Sets for Hemodialysis

Serumwerk Bernburg Vertriebs GmbH

Art.-Nr.	Description
1. 1411	AV/721/SFR/22/R
2. 1412	AV/FRE/R
3. 1415	A-SN/V/799/SFR/22/R
4. 1418	A-SN/V/799/KURZ/R
5. 1432	AV/10100/HDF/SGA/R
6. 1433	AV/SN10100/SGA/R
7. 1435	AV/10100/SGA/R
8. 1436	AV/GAM/R
9. 1473	AV/699/SBR/Dia/R
10. 1472	AV/BRA/R
11. 1481	AV/2/FGH/S/R
12. 1484	AV/DIALYZ-SET/R
13. 1704	Serum-Transducer
14. 1705	AV-Priming Adapter
15. 1741	AV/2000/NI/R
16. 1744	AV/2000/NI/R (K)
17. 1745	A/V-SN/2000/NI/R (K)
18. 1746	AV/NIK/R
19. 1749	AV/2000/NI/R DEHP FREE
20. 9410	AV-03-B
21. 9411	AV-03-SN-B

Bernburg, 25.05.2021



Bernhard Zinner  
-Managing Director-