

# DIN EN ISO 23500-1:2019-11 (English)

## Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements (ISO 23500-1:2019)

---

<b>Contents</b>		<b>Page</b>
European foreword .....		4
7.4.1	Surveillance of water storage tanks .....	30
7.4.2	Surveillance of the water distribution systems .....	30
7.4.3	Surveillance of bacterial control devices .....	31
7.5	Surveillance of concentrate preparation .....	31
7.5.1	Surveillance of mixing systems .....	31
7.5.2	Surveillance of additives .....	32
7.6	Surveillance of concentrate distribution .....	32
7.7	Surveillance of dialysis fluid proportioning .....	32
8	Strategies for microbiological control .....	32
8.1	General .....	32
8.2	Disinfection .....	33
8.2.1	General .....	33
8.2.2	Microbiological aspects of fluid system design .....	33
8.2.3	Disinfection frequency .....	34
8.3	Microbiological surveillance methods .....	35
8.3.1	General .....	35
8.3.2	Sample collection .....	35
8.3.3	Heterotrophic plate count .....	36
8.3.4	Bacterial endotoxin test .....	38
8.3.5	Determination of yeast and mould .....	38
9	Location of and access to the water treatment system .....	38
10	Personnel .....	38
Annex A (informative) Rationale for the development and provisions of this document .....		39
Annex B (informative) Equipment .....		44
Annex C (informative) Surveillance guidelines for water treatment equipment, distribution systems, and dialysis fluid .....		62
Annex D (informative) Strategies for microbiological control .....		67
Annex E (informative) Validation .....		74
Annex F (informative) Special considerations for home haemodialysis .....		77
Annex G (informative) Special considerations for acute haemodialysis .....		83
Bibliography .....		88
7.4	Surveillance of dialysis water storage and distribution .....	30