

ISO/TS 5111:2022-12 (E)

Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
1.1	Inclusions	1
1.2	Exclusions	1
2	Normative references	1
3	Terms and definitions	1
4	Potable water quality	8
4.1	General	8
4.2	Water analysis	8
5	Water quality requirements for different applications/processes	9
6	Water in direct contact with the product being treated	10
6.1	Washer-disinfectors (WDs)	10
6.1.1	General	10
6.1.2	Water quality	10
6.1.3	Final rinse water quality	11
6.1.4	Water quality used during operational qualification (OQ) and performance qualification (PQ) of WDs	11
6.2	Moist heat sterilization using water spray or immersion	11
7	Water to generate steam that contacts the product	11
7.1	Moist heat sterilization	11
7.2	Ethylene oxide (EO) sterilization	12
7.3	Low temperature steam and formaldehyde (LTSF) sterilization	13
7.4	Vaporized hydrogen peroxide (VH202) sterilization	13
8	Water for the equipment without direct contact to the product	14
8.1	Washer-disinfectors (WDs)	14
8.2	Sterilizers	14
8.2.1	General	14
8.2.2	Ethylene oxide (EO) sterilizers	14
8.2.3	Vaporized hydrogen peroxide (VH202) sterilizers	15
9	Water treatment systems	15
9.1	General	15
9.2	Considerations for water treatment	15
9.3	Prefiltration	16
9.4	Carbon filter	16
9.5	Water softeners	16
9.6	Deionization (DI) or demineralization	16
9.7	Reverse osmosis (RO)	16
9.8	Electrodeionization (EDI)	17
9.9	Ultrafiltration	17
9.10	Distillation	17

10	Water distribution and storage	17
10.1	General	17
10.2	Storage vessels	18
10.3	Distribution pipework	18
10.4	Storage and distribution system disinfection	18
10.5	Distribution pumps	18
10.6	Inline ultraviolet (UV) lamps	18
11	Monitoring, maintenance and control	19
11.1	General	19
11.2	Water sampling technique	19
11.2.1	Sampling consistency	19
11.2.2	Sampling containers	19
11.2.3	Flushing	20
11.2.4	Sampling technique	20
11.3	Sterilizers -- Water sampling and tests	20
11.4	Washer-disinfector (WD) -- Water sampling and tests	20
11.4.1	Supply and final rinse water	20
11.4.2	Chemical quality	21
11.4.3	Microbial quality	21
11.4.4	Bacterial endotoxins	22
12	Investigation of out-of-specification results	22
12.1	General	22
12.2	Elements of out-of-specification investigation	22
12.2.1	Interpretation of results	22
12.2.2	Investigation	23
13	Maintaining water quality	23
13.1	Sterilizers	23
13.2	Washer-disinfectors (WDs)	24
14	Cleaning and disinfection of water treatment systems	24
14.1	General	24
14.2	Access to the water treatment system	24
14.3	Cleaning and disinfection methods	25
Annex A (informative) Water quality treatment methods and processes		26
Annex B (informative) Water quality for use in sterilizers and washer-disinfectors (WDs)		28
Annex C (informative) Examples of presentation of water quality issues during the processing of medical devices		33
Bibliography		36