SMP Laboratory Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice		
Subject of testing/product	**Type of activity / properties tested / method**	**Reference documents**
Medical devices	Sterility Direct immersion method	PN-EN ISO 11737-2:2020-11 [1)]
	Presence of microorganisms and coliform index Membrane filtration method Pour plate method	PN-EN ISO 11737-1:2018-03 [1)]
Medical devices, water	Bacterial endotoxin level Gel-clot method Method A: Limit test Method B: Semi-quantitative test	Ph.Eur.11.0, 2023, 2.6.14; 5.1.10 USP 43, NF 38, 2020; <85> and <161> [1)]
Environmental samples - air	Sampling for microbiological testing Volumetric method	LAB-16.12.00, rev.04 as of: 12/07/2022 based on PN-EN 17141:2021-02 [1)]
	Total aerobic bacteria count Plate technique	
Environmental samples - air	Sampling for microbiological testing Gravimetric method	LAB-16.13.00, rev.04 as of: 12/07/2022 based on PN-EN 17141:2021-02 [1)]
	Total aerobic bacteria count Plate technique	
Environmental samples from production areas – surfaces sampling	Sampling for microbiological testing Contact plate method	PN-EN ISO 18593:2018-08 [1)]
	Total aerobic bacteria count Plate technique	LAB-16.10.00, rev.04 as of: 12/07/2022 based on PN-EN 17141:2021-02 [1)]
Environmental samples from production areas -template-limited surface swab - surface swab without using a template defining the sampling area	Sampling for microbiological testing Swab technique	PN-EN ISO 18593:2018-08 [1)]
	Total aerobic bacteria count Membrane filtration method	LAB-16.11.00, rev.04 as of: 12/07/2022 based on PN-EN 17141:2021-02 [1)]
Medical devices	Bacterial endotoxin level Kinetic chromogenic technique Method D: quantitative test	Ph.Eur.11.0, 2023, 2.6.14; 5.1.10 USP 43, NF 38, 2020; <85> and <161> [1)]
Purified water Highly purified water Water for injection Water for extracts	Total aerobic bacteria count Membrane filtration method	Ph.Eur.11.0, 2023 [1)]
Biological indicators of the effectiveness of the sterilization process (Bioindicators)	Presence of the indicator microbes: Bacillus atrophaeus Direct immersion method	LAB-16.09.00 rev.06 as of: 12/07/2022 based on PN-EN ISO 11138-1:2017, PN-EN ISO 11138-7:2019 [1)]

Biological indicators of the effectiveness of the sterilization process (Bioindicators)	Population of the indicator microbes: Bacillus atrophaeus Pour plate method	LAB-16.09.00 rev.06 as of: 12/07/2022 based on manufacturer instruction [1)]

Within the flexible scope, it is allowed to:

1) Using updated methods described in standards / laboratory procedures