

SCOPE OF ACCREDITATION OF TESTING LABORATORY

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	Name and address SteriPack Medical Poland Sp. z o.o. Łęg, ul. Japońska 1 55-220 Jelcz-Laskowice
Identification code *)	Field of testing and item:
B/17	Biological tests of other products (medical devices, substances)
K/17	Microbiological tests of other products (medical devices, bioindicators)
K/57/P	Microbiological tests and sampling objects from production area (air, surfaces)
K/28	Microbiological tests of water

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*) The identification code according to the Annex to document DAB-07, available at PCA website www.pca.gov.pl

This document is an annex to accreditation certificate No. AB 1575 of 9.07.2019

Accreditation cycle from 9.07.2019 to 1.09.2023

The status of accreditation and validity of the scope accreditation can be confirmed at PCA website www.pca.gov.pl

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
	Presence of microorganisms and coliform index Membrane filtration method Direct immersion method	PN-EN ISO 11737-1:2018-03
Medical devices, substances	Bacterial endotoxin level Gel-clot method Method A: Limit test Method B: Semi-quantitative test	Ph.Eur.10.0, 2020, 2.6.14; 5.1.10 FP XI 2017, 2.6.14; 5.1.10 USP 43, NF 38, 2020; <85> and <161>
Environmental samples - air	Sampling for microbiological testing Volumetric method	LAB-16.12.00, rev.03 as of: 15/01/2019
	Total aerobic bacteria count Scope: from 1CFU/1m ³ Plate technique	
Environmental samples - air	Sampling for microbiological testing Gravimetric method	LAB-16.13.00, rev.03 as of: 15/01/2019
	Total aerobic bacteria count Scope: from 1CFU/1m ³ Plate technique	
Environmental samples from production areas – surfaces sampling	Sampling for microbiological testing Contact plate method	PN-EN ISO 18593:2018-08
	Total aerobic bacteria count Scope: from 1CFU/25cm ² Plate technique	LAB-16.10.00, rev.03 as of: 15/01/2019
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
	Total aerobic bacteria count Scope: from 1CFU/100cm ² (surface defined with template) from 1CFU/tested surface (surface not defined with a template) Membrane filtration method	LAB-16.11.00, rev.03 as of: 15/01/2019
Medical devices	Bacterial endotoxin level Kinetic chromogenic technique Method D: quantitative test	Ph.Eur.10.0, 2020, 2.6.14; 5.1.10 FP XI 2017, 2.6.14; 5.1.10 USP 43, NF 38, 2020; <85> and <161>

Purified water Highly purified water Water for injection Water for extracts	Total aerobic bacteria count Scope: from 1CFU/100mL Membrane filtration method	Ph.Eur.10.0, 2020
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.04 as of: 01/07/2021 based on PN-EN ISO 11138-1:2017, PN-EN ISO 11138-7:2019
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.04 as of: 01/07/2021 based on manufacturer instruction