

SCOPE OF ACCREDITATION OF TESTING LABORATORY

No. AB 1575

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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, B/28 K/3, K/17, K/28 K/57/P	Biological tests of other products (medical devices); water Microbiological tests of biological items and materials for testing; other products (medical devices), water Microbiological tests and sampling objects from production area (air, surfaces)

Page version: A

*) 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 21.08.2023 to 1.09.2027

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
<i>Flexible scope of accreditation</i> ¹⁾		
Medical devices	Sterility Direct immersion method	PN-EN ISO 11737-2 ¹⁾ Ph.Eur., 2.6.1 ¹⁾
	Presence of microorganisms and coliform index Membrane filtration method Pour plate method	PN-EN ISO 11737-1 ¹⁾ Ph.Eur., 2.6.12 ¹⁾
Medical devices, water	Bacterial endotoxin level Gel-clot method Method A: Limit test Method B: Semi-quantitative test	Ph.Eur., 2.6.14; 5.1.10 USP <85> and <161>
Environmental samples - air	Sampling for microbiological testing Volumetric method	LAB-16.12.00 ¹⁾
	Total aerobic bacteria count Plate technique	
Environmental samples - air	Sampling for microbiological testing Gravimetric method	LAB-16.13.00 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 ¹⁾
	Total aerobic bacteria count Plate technique	LAB-16.10.00 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 ¹⁾
	Total aerobic bacteria count Membrane filtration method	LAB-16.11.00 ¹⁾
Medical devices	Bacterial endotoxin level Kinetic chromogenic technique Method D: quantitative test	Ph.Eur., 2.6.14; 5.1.10 USP <85> and <161>
Purified water Highly purified water Water for injection Water for extracts	Total aerobic bacteria count Membrane filtration method	Ph.Eur. ¹⁾
Biological indicators of the effectiveness of the sterilization process (Bioindicators)	Presence of the indicator microbes: Bacillus atropheus Direct immersion method	LAB-16.09.00 based on PN-EN ISO 11138-1, PN-EN ISO 11138-7 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 based on manufacturer instructions
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Within the flexible scope, it is allowed to:

- 1) Using updated methods described in standards / laboratory procedures