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PCA

Scope of Accreditation No. AB 1575-/-

SCOPE OF ACCREDITATION OF TESTING LABORATORY No. AB 1575

issued by
THE POLISH CENTRE FOR ACCREDITATION
01-382 Warszawa, ul. Szczotkarska 42

Edition No. 7 Date of issue: 9 July 2019

[GRAPHICS]: POLISH CENTRE FOR ACCREDITATION; TESTING AB 1575	Name and address SteriPack Medical Poland Sp. z o. o. Łęg, ul. Japońska 1 55-220 Jelcz-Laskowice
Field / Subject of Testing Id. Code	Field/Subject of Testing:
B/17 K/17 K/9/P K/9	Biological testing / other products (medical devices, substances) Microbiological testing / other products (medical devices) Microbiological testing and environmental sampling (air, surfaces) Microbiological testing of water

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Hanna Tugi, Head of Food Testing and Certification Accreditation Department; *[handwritten signature]*-/
*[Round seal of the Polish Centre for Accreditation with the Polish national emblem in the middle *1*]*-/

This document is an addendum to Accreditation Certificate No. AB 1575 as of 09-07-2019.
Accreditation cycle: from 09-07-2019 to 01-09-2023.

The accreditation status and the validity of the accreditation scope can be verified at the Polish Centre for Accreditation's website at www.pca.gov.pl.

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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 culture method	PN-EN ISO 11737-2:2010
	Presence of microorganisms and coliform index Membrane filtration method Direct culture 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. 9, 2017,2.6.14, 5.1.10 FP X 2014, 2.6.14; 5.1.10 USP 40, NF 35, 2017 <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 1 CFU/1 m ³ Plate technique	
Environmental samples from production areas – surface sampling	Sampling for microbiological testing Replica-plate technique	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 1 CFU/100 cm ² (surface defined with a template) from 1 CFU/ 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. 9, 2017,2.6.14, 5.1.10 FP X 2014, 2.6.14; 5.1.10 USP 40, NF 35, 2017 <85> and <161 >
Purified water Highly purified water Water for injection Water for extracts	Total aerobic bacteria count Scope: from 1 CFU/100mL Membrane filtration method	Ph.Eur. 9.0, 2017



**List of Revisions
in Scope of Accreditation no. AB 1575**

Revision status: original version – A

The revision status is hereby approved.

Hanna Tugi, Head of Food Testing and Certification Accreditation Department; *[handwritten signature]*-/-

This 9th day of July 2019-/-

*[Round seal of the Polish Centre for Accreditation with the Polish national emblem in the middle *1*]*-/-

[Hologram with number 018639]-/-

Edition no. 7 ,9 July 2019-/-

I, Agnieszka Kozłowska, the undersigned and duly commissioned Certified Translator of the English Language, entered under no. TP/98/14 into the list of Certified Translators maintained by the Polish Minister of Justice, do hereby confirm that the above translation is a complete and true version of the original document in the Polish language.

Repertory No. 616/2019

Wrocław, this 24th day of July, 2019.

