

Certified Translation from the Polish language

[Header on each page of the 3-page document]: PCA, Scope of Accreditation No. AB 1575-/-

**SCOPE OF ACCREDITATION-/-
OF TESTING LABORATORY-/-
NO. AB 1575-/-**

issued by

POLISH CENTRE FOR ACCREDITATION-/-
01-382 Warsaw, ul. Szczotkarska 42-/-

Edition No. 4, Date of issue: 17th November 2017-/-

[Logo]: PCA 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
Testing field / object identification code	Testing field / object:
B/17 K/17 K/9/P	Biological testing / other products (medical devices, substances) Microbiological testing / other products (medical devices) Microbiological testing and environmental sampling (air, surfaces)

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

Lucyna Olborska, Director; [illegible signature]-/-

This document is an attachment to Accreditation Certificate No. AB 1575 as of 2nd September 2015.

The accreditation status and the current scope of accreditation can be viewed at PCA website
www.pca.gov.pl -/-



Testing Laboratory Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice		
Object / product tested	Type of activity/ Tested characteristics / method	Reference documents
Medical devices	Sterility Direct immersion method	PN-EN ISO 11737-2:2010
	Presence and titre of microorganisms Membrane filtration method Pour plate method	PN-EN ISO 11737-1:2007
Medical devices, substances	Bacterial endotoxins 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. 02 of 01/08/2017
	Total aerobic microbial count Range: from 1CFU/1m ³ Plate method	
Environmental samples – air	Sampling for microbiological testing Gravimetric method	LAB-16.13.00, rev. 02 of 01/08/2017
	Total aerobic microbial count Range: from 1CFU/1m ³ Plate method	
Environmental samples from production areas - print from a surface	Sampling for microbiological testing Contact plates method	PN ISO 18593:2005P
	Total aerobic microbial count Range: from 1CFU/25cm ² Plate method	LAB-16.10.00, rev. 02 of 01/08/2017
Environmental samples from production areas - surface swab limited by template - surface swab not limited by template including hands (fingerprint)	Sampling for microbiological testing Swab method	PN ISO 18593:2005P
	Total aerobic microbial count Range: from 1CFU /100 cm ² (surface limited by template) from 1 CFU/tested surface (surface not limited by template) Membrane filtration method	LAB-16.11.00, rev. 02 of 01/08/2017
Medical devices	Bacterial endotoxins Kinetic chromogenic method 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>

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**List of Amendments
to Scope of Accreditation No. AB 1575**

Status of amendments: original version – A-/-

[Graphic sign with the Polish national emblem]: PCA 009467-/-

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The status of amendments is hereby confirmed.

Lucyna Olborska, Director; [illegible signature]-/-

Date: 17.11.2017-/-

[Footer on each page of the 3-page document]: Edition No. 4, 17th November 2017; [page number from 1 to 3]-/-

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. 204/2018

Wrocław, this 19th day of February, 2018.

