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**CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE**

PCA

The scope of accreditation No. AB 1575

THE SCOPE OF ACCREDITATION

OF THE RESEARCH LABORATORY

NO. AB 1575

issued by

POLISH CENTRE FOR ACCREDITATION

01-382 Warszawa, ul. Szczotkarska 42

Issue No. 1 Date of issuance: 2<sup>nd</sup> September 2015

<i>[logo of the Polish Centre for Accreditation]</i> AB 1575	Name and address SteriPack Medical Poland Sp. z o.o. Łęg, ul. Japońska 1 55-220 Jelcz-Laskowice
Code for identification of the field/subject of the research	Field/subject of the research
B/17 K/17	Biological research/other goods (medical goods, substances) Micro-biological research/other goods (medical goods)

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*[a red, round stamp of the Polish Centre for Accreditation with the national emblem in the centre]*

Head of the Department for Accreditation of Laboratories

*[an illegible signature]*

Tadeusz Matras

This document is an enclosure to Accreditation Certificate No. AB 1575 dated 2<sup>nd</sup> September 2015.

The status of accreditation as well as updates of the accreditation scope can be confirmed on the PCA website:

[www.pca.gov.pl](http://www.pca.gov.pl)

Department for Accreditation of Laboratories

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Laboratory test Łęg, ul. Japońska1, 55-220 Jelcz-Laskowice		
Subject of the research/goods	Type of activity/examination of characteristics/method	Reference documents
Medical goods	Sterility Direct culture method	PN-EN ISO 11737-2:2010
	Presence and titre of micro-organisms Membrane filtration method Direct culture method	PN-EN ISO 11737-1:2010
Medical goods, substances	Level of bacteria endotoxins Gel technique Method A: Limit test Method B: Semi-qualitative test	Ph.Eur:2.6.14; 01/2010:20614 corr.7.0 FP:2.6.14; 01/2010:20614 zm.7.0 USP 32 NF 27,2009; <85> i<161>

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