Certificate

Management system as per

ISO 13485:2016 (MDSAP)

The Auditing Organization TUV USA, Inc. hereby confirms as a result of the audit, assessment, and certification decision according to ISO/IEC 17021-1:2015, that the organization

SteriPack Medical Poland Sp. z o.o.
also registered under **S.M.P. Sp. z o.o.**
Łęg, ul. Japońska 1
55-220, Jelcz-Laskowice
Poland
[Facility ID: F003976]

Operates a management system in accordance with the requirements of ISO 13485:2016 (MDSAP) and will be assessed for conformity within the 3-year term of validity of the certificate for the following jurisdictions:
Canada: Medical Devices Regulations – Part 1- SOR/98-282.
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Scope

Manufacturing and Distribution of Hypodermic Needles

Certificate Registration No. 25-1614-M
Project No. 25-4132 RC-CSA

Issue Date:	2025-06-30
Reissue Date:	--
Expiry Date:	2028-06-29
Initial Certification Date:	2018-06-19

Salem, NH; 2025-06-25, Edition 1

Auditing Organization TUV USA, Inc.

The validity of this certificate may be obtained by contacting TUV USA at: +1 (603) 870-8023 (option 1) or via Email: medical-usa@tuv-nord.com

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MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

TUV USA, Inc. is recognized under the Medical Device Single Audit Program