

Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **19-1637-M**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under the following jurisdictions:

Canada: Medical Devices Regulations – Part 1- SOR/98-282. **USA:** United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

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**

Additional sites covered by QM System: **N/A**

List of Products: **See Annex 1**

Scope:

Manufacturing and Distribution of Hypodermic Needles

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

TUV USA, Inc. (a Member of the TÜV NORD Group)

215 Main Street, Suite 1, Salem, NH 03079, USA

Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: **21-3977 RC-SA3**

Initial Certification Date: **2019-12-20**

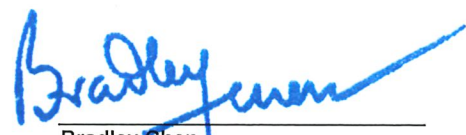
Current Cycle Start Date: **2022-06-30**

Effective Date:

2022-06-30 / ed. 2

Valid Until:

2025-06-29



Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.

Annex 1, page 1 of 1

(Annex 1 MUST be displayed with the main certificate)

Certificate Registration No. : 19-1637-M / ed. 2
Company Name: SteriPack Medical Poland Sp. z o.o.
also registered under S.M.P. Sp. z o.o.
Central (HQ) Office Address: Łęg, ul. Japońska 1, 55-220, Jelcz-Laskowice, Poland



Products

UMDNS

GMDN

Safety Needles

12-745

59230

---End of list---

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