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

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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.

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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