

Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **18-1628-Q**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with **ISO 13485:2016** for Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes.

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

Additional sites covered by QM System: **None**

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 TUV 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



Audit Report Reference No.: **18-8067 TNG-TRF**

Certificate Initial Issue Date: **06-DEC-2018**

Certificate Revised Date: **N/A**

Effective Date:
06-DEC-2018 / ed. 1

Valid Until:
18-JUN-2021



Bradley Chen
Director, Medical Products Division
TUV USA, Inc.