**CERTIFICATE No. GIF-IW-400/0432_01_01/04/105/16**

*Main Pharmaceutical Inspector*

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

**Part 1**

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended

**Main Pharmaceutical Inspector**
/the Competent Authority of Poland/

confirms the following:

the manufacturer

**SteriPack Medical Poland Sp. z o.o.**
**Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice, POLAND**

site address

**SteriPack Medical Poland Sp. z o.o.**
**Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice, POLAND**

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **026/0432/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2008, No. 45, item 271 with amendments).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **16-17/02/2016**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

acting Main Pharmaceutical Inspector

date: 2016 -04- 22

Zbigniew Niewójt

**Main Pharmaceutical Inspectorate**
**ul. Senatorska 12, 00-082 Warszawa, Poland**
**Tel. +48 22 635 99 51, fax. +48 22 635 99 57**

**Zbigniew Niewójt**
**Main Pharmaceutical Inspector**

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**Part 2**

| Human Medicinal Products |
|---|

| 1 MANUFACTURING OPERATIONS | |
|---|---|
| **1.5** | **Packaging** |
| | **1.5.2 Secondary packing** |
| **1.6** | **Quality control testing** |
| | **1.6.3 Chemical/Physical** |

**Any restrictions or clarifying remarks related to the scope of this certificate:**

Point 1.6.3 concerns functional tests of autoinjector with medicinal product.

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

acting Main Pharmaceutical Inspector

Zbigniew Niewójt

date: 2016 -04- 22

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