

CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE

MAIN PHARMACEUTICAL INSPECTORATE

[national emblem of the Republic of Poland]

Main Pharmaceutical Inspectorate
GIF-IW-400/0432/01/87/6/16

DECISION

Pursuant to Art. 38 para. 1 and 2, Art.41 para. 4 of the Act dated 6th September 2001 – Pharmaceutical Law (Journal of Laws 2008, No. 45, item 271 as amended) and Art. 104 § 1 and Art. 155 of the Act dated 14th June 1960- the Code for Administrative Proceedings (Journal of Laws 2013 item 267 as amended)

MAIN PHARMACEUTICAL INSPECTORATE

changes

The authorisation for manufacturing or importation of medicinal product No. 026/0432/15 issued for SteriPack Medical Poland Sp. z o.o pursuant to decision: GIF-IW-400/0432/01/485/01/26/15 dated 25th June 2015

by giving it the wording as follows:

MANUFACTURING OR IMPORTATION AUTHORISATION

1. Authorisation number: 026/0432/15
2. Name of authorization holder: SteriPack Medical Poland Sp. z o.o
3. Address of manufacturing or importing site: Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice- a manufacturing site
4. Address of manufacturer or importer: Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice
5. Scope of authorization and dosage forms: human medicinal products: annex 1
6. Legal basis of authorization:
Art. 38 para. 1 and 2 of the Act dated 6th September 2001 – Pharmaceutical Law (Journal of Laws 2008, No. 45, item 271 as amended)
7. Name of Main Pharmaceutical Inspector:
Zbigniew Niewójt
8. Signature

Fulfilling duties of the Main Pharmaceutical Inspector

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Zbigniew Niewójt

[a round stamp of the Main Pharmaceutical Office]

9. Date: 19th April 2016



Beata Koźmińska

Justification

In the letter filed in the Main Pharmaceutical Office on 26th January 2016 SteriPack Medical Poland Sp. z o.o applied for making changes to the authorization for manufacturing or importation of medicinal product No. 026/0432/15 dated 25th June 2015 by extending the scope of manufacturing human medicinal products with points as follows:

1.6. Quality control testing

1.6.3. Chemical/Physical

Including a remark:

- Point 1.6.3. concerns carrying out functional tests of the auto-injector with medicinal product

Having considered the application, the Main Pharmaceutical Inspector agreed to the above changes.

Pursuant to Art. 107 § 4 of the Code for Administrative Proceedings the Main Pharmaceutical Inspector has renounced a justification for this decision as it accounts for the party's request in a complete manner.

Instruction:

Pursuant to Art. 127 § 3 of the Code for Administrative Proceedings, within 14 days as of delivering this decision, the party may apply to the Main Pharmaceutical Inspector for reconsidering the matter.

Fulfilling duties of the Main Pharmaceutical Inspector

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Zbigniew Niewójt

[a round stamp of the Main Pharmaceutical Office]

Copy to:

1. The Party: SteriPack Medical Poland Sp. z o.o
Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice
2. Files



Beata Zolmirska

Annex 1

SCOPE OF AUTHORISATION AND TYPE AND FORM OF MEDICINAL PRODUCTS

Name and address of the manufacturing/ importing site:

SteriPack Medical Poland Sp. z o.o

Łęg, ul. Japońska 1, 55-220 Jelcz-Laskowice

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing medicinal products

Part 1 Manufacturing Operations

1.5. Packaging

1.5.2. Secondary packing

1.6 Quality control testing

1.6.3. Chemical/Physical

Reservations or clarifying remarks related to the scope of these Manufacturing Operations

Point 1.6.3 concerns functional tests of auto-injector with medicinal product

Fulfilling duties of the Main Pharmaceutical Inspector

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Zbigniew Niewójt

[a round stamp of the Main Pharmaceutical Office]

[all the pages display the address and telephone numbers of the Main Pharmaceutical Office

: ul. Senatorska 12, 00-082 Warsaw, Poland, tel. +48 22 635 99 66, fax. +48 22 831 02 44, www.gif.gov.pl, e-mail: gif@gif.gov.pl]

Repertory No. 14/2016

I, Beata Koźmińska, undersigned and duly commissioned Sworn Translator of the English language do hereby confirm that the above translation is a complete and true version of the document in the Polish language.

Fee according to repertory entry.

Wrocław, this 27th April 2016

