

## ***Health And Youth Care Inspectorate***

CERTIFICATE NUMBER: **NL/H 22/2040793**

# **CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**<sup>1,2</sup>

### **Part 1**

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

The competent authority of Netherlands confirms the following:

The manufacturer: ***Sharp Packaging Services LLC***

Site address: ***7451 Keebler Way, Allentown, PA, 18106-9302, United States***

OMS Organisation Id. / OMS Location Id.: ***ORG-100041546 / LOC-100068654***

DUNS Number: ***14-369-6495***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-03-18***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC<sup>3</sup>

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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>).

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 EudraGMDP. If it does not appear, please contact the issuing authority.

<sup>1</sup>The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

<sup>2</sup>Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

<sup>3</sup>These requirements fulfil the GMP recommendations of WHO.

## Part 2

Human Medicinal Products

### 1 MANUFACTURING OPERATIONS

#### 1.5 Packaging

1.5.2 Secondary packaging

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
<i>Building 04, 7384 Penn Drive, Allentown</i>	<i>all</i>	<i>N/A</i>	<i>N/A</i>	<i>confidential</i>
<i>Warehouse facility (building 30): 7339 Industrial Boulevard, Allentown</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>confidential</i>

Clarifying remarks (for public users)

*Restricted to secondary packaging activities (labelling and packaging) at Building 04, and to warehousing activities in Building 30.*

2022-06-14

Name and signature of the authorised person of the  
Competent Authority of Netherlands

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*Confidential*  
*Health and Youth Care Inspectorate – Pharmaceutical*  
*Products*  
Tel: *Confidential*  
Fax: *Confidential*

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