

## ***Regional Council Darmstadt***

CERTIFICATE NUMBER: **DE\_HE\_01\_GMP\_2019\_0145**

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

### **Part 1**

Issued following an inspection in accordance with :

Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Germany confirms the following:

The manufacturer: ***B. Braun Melsungen AG***

Site address: ***Carl-Braun-Strasse 1, Melsungen, Hessen, 34212, Germany***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **DE\_HE\_01\_MIA\_2019\_0059** in accordance with Art. 44 of Directive 2001/82/EC transposed in the following national legislation:

***§ 13 Abs. 1 Arzneimittelgesetz (manufacture) and § 72 Arzneimittelgesetz (import)***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-05-22**, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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. 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 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

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

## Part 2

Veterinary Medicinal Products	
<b>1 MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	<i>1.1.3 Batch certification</i>
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packing</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Clarifying remarks (for public users)

***Partial testing in contract laboratories according to sect 14 para 4 German Drug Law (see annex 4 of manufacturers authorisation). Holding in external warehouses, see separate document.***

2019-10-07

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

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**Confidential**  
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