



Chief Pharmaceutical Inspector

IWPS.405.2.2020.MS.1  
WTC/0499\_01\_01/123

## 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

### Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

**Grand Medical Poland Sp. z o.o.**  
**ul. Faradaya 2, 03-233 Warszawa, POLSKA**

site address

**Grand Medical Poland Sp. z o.o.**  
**ul. Faradaya 2, 03-233 Warszawa, POLSKA**

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **136/0499/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6<sup>th</sup> of September 2001 (Journal of Laws from 2020, item 944).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **27-31/07/2020**, 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.



date: 2020 -11- 2 6

Chief Pharmaceutical Inspectorate  
ul. Senatorska 12, 00-082 Warszawa, Poland  
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**Paweł Piotrowski**  
Chief Pharmaceutical Inspector

## Part 2

Human Medicinal Products

## 1 MANUFACTURING OPERATIONS

1.2	<b>Non-sterile products</b>
	<b>1.2.1 Non-sterile products</b> 1.2.1.13 Tablets <b>1.2.2 Batch certification</b>
1.5	<b>Packaging</b>
	<b>1.5.1 Primary packing</b> 1.5.1.13 Tablets <b>1.5.2 Secondary packing</b>
1.6	<b>Quality control testing</b>
	<b>1.6.3 Chemical/Physical</b>

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

**The certificate was issued on the basis of remote inspection.**


**This certificate should not be relied upon to reflect the compliance status if more than one and half year have elapsed since the date of the inspection.**



date:

2020 -11- 2 6

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