

**Javna agencija Republike Slovenije za zdravila in medicinske pripomočke**CERTIFICATE NUMBER: **401-0019/2009-4**

## 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

The competent authority of Slovenia confirms the following:

The manufacturer: **Vitiva, proizvodnja in storitve d.d.**

Site address: **Nova vas 98, Markovci, 2281, Slovenia**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **41-117/07-03** in accordance with Art. 40 of Directive 2001/83/EC .

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2009-06-12** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC
- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/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, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

**Part 2**

Manufacture of active substance. Names of substances subject to inspection:

- **HELENIEN CONCENTRATE(en)**
- **DIOL LACTONE(en)**

**2009-07-08**

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

**Mr Janez Obreza**

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