



**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 *Denmark* confirms the following:

The manufacturer Pharmacosmos A/S

Site address Rørvangsvej 30  
4300  
Holbæk  
Denmark

is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: *(Consolidated) Medicinal Products Act, 2005, as amended.*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2011/03/03, it is considered that it complies with the Good Manufacturing Practice requirements referred to in 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:  
Iron dextran powders of various selected strengths, incl. iron isomaltoside powders

Any restrictions or clarifying remarks related to the scope of this certificate:  
None

Date: 7 April 2011

Name and signature of the authorised person  
of the competent authority of Denmark:

f:   
.....  
Lone Cleveland Andersen

The Danish Medicines Agency

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