



EUROSTATION II
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**Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten -
Agence Fédérale des Médicaments et des Produits de Santé**

CERTIFICATE NUMBER: *BE/2010/021*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Belgium confirms the following:

The manufacturer: **STERIGENICS**

Site address: **1003 Lakeside Drive, Gurnee, IL, 60031, United States**

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 33(2) of Regulation 726/2004/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2010-04-15** , it is considered that it complies with :

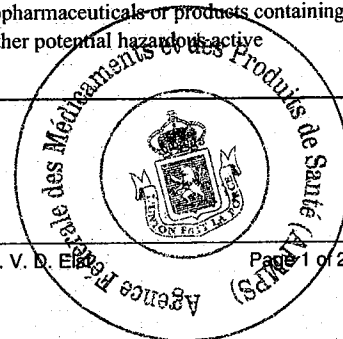
This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified with the issuing authority.

Part 2

Veterinary Medicinal Products

1 Manufacturing Operations

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potential hazardous active ingredients this should be stated under the relevant produce type and dosage form;




1.4	Other products or manufacturing activity (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc).
	1.4.2 <i>Sterilisation of active substance/ excipients/ finished product</i> 1.4.2.5 Gamma irradiation

Any restrictions related to the scope of this certificate :

This inspection was a routine inspection on the request of the European Medicines Agency (EMA). It is a product related GMP inspection related to Naxcel (= cephalosporin) suspension for injections. (EMEA/V/C/79 NAXCEL suspension for injection)

2011-01-14

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



Dr Josiane Van Der Elst
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