



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC.

The competent authority of *Denmark* confirms the following:

The manufacturer Sterigenics Denmark A/S

Site address Aa. Louis-Hansens Allé 11
 3060
 Espergærde
 Denmark

has been inspected under the national inspection programme in connection with manufacturing authorisation no. 16301 in accordance with Art. 13 of Directive 2001/20/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 2010/09/30, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC2.

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

Certificate No. DK IMP 00013711

Human Investigational 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 are specified under the relevant items.
- If the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients this is stated under the relevant product type and dosage form.

1.4	Other investigational medicinal products or manufacturing activity
	1.4.2 Sterilisation of active substances/excipients/finished product: <i>Sterilisation of active substances/excipients/finished product:</i>
	1.4.2.6 Electron beam <i>Electron beam</i> + <i>Irradiation of medicinal components</i>

1.6	Quality control testing
	1.6.1 Microbiological: sterility <i>Microbiological: sterility</i>
	1.6.2 Microbiological: non-sterility <i>Microbiological: non-sterility</i>

2 IMPORTATION OF MEDICINAL PRODUCTS

- Authorised importation activities without manufacturing activity
- Authorised importation activities include storage and distribution unless informed to the contrary

2.1	Quality control testing of imported investigational medicinal products
	2.1.1 Microbiological: sterility <i>Microbiological: sterility</i>
	2.1.2 Microbiological: non-sterility <i>Microbiological: non-sterility</i>

Manufacture of active substance. Names of substances subject to inspection:
None

Any restrictions or clarifying remarks related to the scope of this certificate:
Not applicable
Date: 2011/08/05

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


.....
Claus Mortensen

The Danish Medicines Agency

E-mail: dkma@dkma.dk
Fax: + 44 88 91 95



Certificate No. DK H 00013711

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 *Sterigenics Denmark A/S*

Site address *Aa. Louis-Hansens Allé 11*
 3060
 Espergærde
 Denmark

has been inspected under the national inspection programme in connection with manufacturing authorisation no. 16301 in accordance with Art. 40 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 2010/09/30, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC2.

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

Certificate No. DK H 00013711

Human 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 are specified under the relevant items.
- If the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients this is stated under the relevant product type and dosage form.

1.4 Other products or manufacturing activity

1.4.2 Sterilisation of active substances/excipients/finished product: *Sterilisation of active substances/excipients/finished product:*

1.4.2.6 Electron beam *Electron beam*
+ Irradiation of medicinal components

1.6 Quality control testing

1.6.1 Microbiological: sterility *Microbiological: sterility*

1.6.2 Microbiological: non-sterility *Microbiological: non-sterility*

2 IMPORTATION OF MEDICINAL PRODUCTS

- Authorised importation activities without manufacturing activity
- Authorised importation activities include storage and distribution unless informed to the contrary

2.1 Quality control testing of imported medicinal products

2.1.1 Microbiological: sterility *Microbiological: sterility*

2.1.2 Microbiological: non-sterility *Microbiological: non-sterility*

Manufacture of active substance. Names of substances subject to inspection:
None

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

Not applicable

Date: 2011/08/05

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

.....
Claus Mortensen

The Danish Medicines Agency

E-mail: dkma@dkma.dk

Fax: + 44 88 91 95



Certificate No. DK V 00013711

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 *Denmark* confirms the following:

The manufacturer Sterigenics Denmark A/S

Site address Aa. Louis-Hansens Allé 11
 3060
 Espergærde
 Denmark

has been inspected under the national inspection programme in connection with manufacturing authorisation no. 16301 in accordance with Art. 44 of Directive 2001/82/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 2010/09/30, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC2.

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

Certificate No. DK V 00013711

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 are specified under the relevant items.
- If the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients this is stated under the relevant product type and dosage form.

1.4 Other products or manufacturing activity

1.4.2 Sterilisation of active substances/excipients/finished product: *Sterilisation of active substances/excipients/finished product:*

1.4.2.6 Electron beam *Electron beam*
+ *Irradiation of medicinal components*

1.6 Quality control testing

1.6.1 Microbiological: sterility *Microbiological: sterility*

1.6.2 Microbiological: non-sterility *Microbiological: non-sterility*

2 IMPORTATION OF MEDICINAL PRODUCTS

- Authorised importation activities without manufacturing activity
- Authorised importation activities include storage and distribution unless informed to the contrary

2.1 Quality control testing of imported medicinal products

2.1.1 Microbiological: sterility *Microbiological: sterility*

2.1.2 Microbiological: non-sterility *Microbiological: non-sterility*

Manufacture of active substance. Names of substances subject to inspection:
None

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

Not applicable

Date: 2011/08/04

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

.....
Claus Mortensen

The Danish Medicines Agency

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