

**GMP- Certificate Nr: NL/H 11/0055**

PUBLIC HEALTH SUPERVISORY SERVICE  
HEALTH CARE INSPECTORATE



**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**

**Part 1**

**Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC**

The competent authority of The Netherlands confirms the following:

The manufacturer **Linde Gas Therapeutics Benelux B.V.**

Site address **De Keten 7  
5651 GJ Eindhoven  
The Netherlands**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **3995 F**, in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: The medicines Act, article 100.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **1 March 2011**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice 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, 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.

Issue Date: 1 August 2011  
Signature:

G.J. van Ringen, Pharmacist  
Inspector, Health Care Inspectorate, The Netherlands  
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**Part 2**

<input checked="" type="checkbox"/> Human Medicinal Products <input type="checkbox"/> Veterinary Medicinal Products <input type="checkbox"/> Human Investigational Medicinal Products
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**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 or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form.

1.1	Sterile Products	Yes	No
		<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.1.1 Aseptically prepared (list of dosage forms)</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.1.1 Large volume liquids	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.1.2 Lyophilisates	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.1.3 Semi-solids	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.1.4 Small volume liquids	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.1.5 Solids and implants	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.1.6 Other aseptically prepared products: <free text>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.1.2 Terminally sterilised (list of dosage forms)</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.2.1 Large volume liquids	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.2.2 Semi-solids	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.2.3 Small volume liquids	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.2.4 Solids and implants	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.1.2.5 Other terminally sterilised prepared products <free text>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.1.3 Batch certification only</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

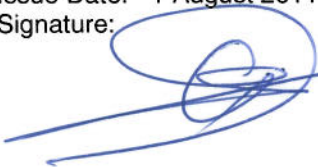
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1.2	Non-sterile products	Yes	No
		<input checked="" type="checkbox"/>	<input type="checkbox"/>
	<i>1.2.1 Non-sterile products (list of dosage forms)</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	1.2.1.1 Capsules, hard shell	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.2 Capsules, soft shell	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.3 Chewing gums	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.4 Impregnated matrices	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.5 Liquids for external use	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.6 Liquids for internal use	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.7 Medicinal gases	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	1.2.1.8 Other solid dosage forms	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.9 Pressurised preparations	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.10 Radionuclide generators	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.11 Semi-solids	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.12 Suppositories	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.13 Tablets	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.14 Transdermal patches	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.15 Intraruminal devices	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.16 Veterinary premixes	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.2.1.17 Other non-sterile medicinal product <free text >	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.2.2 Batch certification only</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1.3	Biological medicinal products	Yes	No
		<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.3.1 Biological medicinal products</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.1.1 Blood products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.1.2 Immunological products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.1.3 Cell therapy products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.1.4 Gene therapy products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.1.5 Biotechnology products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.1.6 Human or animal extracted products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.1.7 Other biological medicinal products <free text >	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.3.2 Batch certification only (list of product types)</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.2.1 Blood products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.2.2 Immunological products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.2.3 Cell therapy products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.2.4 Gene therapy products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.2.5 Biotechnology products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.2.6 Human or animal extracted products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.3.2.7 Other biological medicinal products <free text >	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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<b>1.4</b>	<b>Other products or manufacturing activity</b> (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), herbal or homeopathic products, bulk or total manufacturing, etc).	<b>Yes</b>	<b>No</b>
		<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.4.1 Manufacture of:</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.4.1.1 Herbal products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.4.1.2 Homoeopathic products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.4.1.3 Biological active starting materials	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.4.1.4 Other <free text >	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.4.2 Sterilisation of active substances/excipients/finished product:</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.4.2.1 Filtration	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.4.2.2 Dry heat	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.4.2.3 Moist heat	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.4.2.4 Chemical	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.4.2.5 Gamma irradiation	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.4.2.6 Electron beam	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.4.3 Others &lt;free text&gt;</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>1.5</b>	<b>Packaging only</b>	<b>Yes</b>	<b>No</b>
		<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.5.1 Primary packing</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.1 Capsules, hard shell	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.2 Capsules, soft shell	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.3 Chewing gums	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.4 Impregnated matrices	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.5 Liquids for external use	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.6 Liquids for internal use	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.7 Medicinal gases	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.8 Other solid dosage forms	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.9 Pressurised preparations	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.10 Radionuclide generators	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.11 Semi-solids	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.12 Suppositories	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.13 Tablets	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.14 Transdermal patches	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.15 Intraruminal devices	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.16 Veterinary premixes	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.5.1.17 Other non-sterile medicinal products <free text >	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	<i>1.5.2 Secondary packing</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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1.6	Quality control testing	Yes	No
		<input checked="" type="checkbox"/>	<input type="checkbox"/>
	1.6.1 Microbiological: sterility	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.6.2 Microbiological: non-sterility	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	1.6.3 Chemical/Physical	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	1.6.4 Biological	<input type="checkbox"/>	<input checked="" type="checkbox"/>

**2 IMPORTATION OF MEDICINAL PRODUCTS\***

- any importation activity in relation to imported product should be entered under the relevant product categories in this section. Importation activities relating to partially manufactured product should also be included in this section.
- importation activities include storage and distribution unless informed to the contrary

2.1	Quality control testing of imported medicinal products	Yes	No
		<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.1.1 Microbiological: sterility	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.1.2 Microbiological: non-sterility	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.1.3 Chemical/Physical	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.1.4 Biological	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2.2	Batch certification of imported medicinal products	Yes	No
		<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.1 <i>Sterile Products</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.1.1 Aseptically prepared	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.1.2 Terminally sterilised	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.2 <i>Non-sterile products</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.3 <i>Biological medicinal products</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.3.1 Blood products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.3.2 Immunological products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.3.3 Cell therapy products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.3.4 Gene therapy products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.3.5 Biotechnology products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.3.6 Human or animal extracted products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	2.2.3.7 Other biological medicinal products <free text >	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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2.2.4	<i>Other importation activities</i> (any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products, etc.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2.2.4.1	Radiopharmaceuticals/Radionuclide generators	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2.2.4.2	Medicinal gases	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2.2.4.3	Herbal products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2.2.4.4	Homoeopathic products	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2.2.4.5	Biological active starting materials	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2.2.4.6	Other <free text >	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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

N.a.

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