



*Ravimiamet*  
**Estonian State Agency of Medicines**

CERTIFICATE NUMBER: *JV-16/23/8*

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER <sup>(1), (2)</sup>**

**Part 1**

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

The competent authority of Estonia confirms the following:

The manufacturer: *Elme Messer Gaas AS*

Site address: *Auvere küla, Narva-Jõesuu linn, Ida-Viru maakond 40107, Estonia*

OMS Organisation Id. / OMS Location Id.: **ORG-100002577 / LOC-100002702**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2023-05-19**, it is considered that it complies with:

The principles of GMP for active substances (3) referred to in Article 47 of Directive 2001/83/EC transposed in the following national legislation:

***National legislation – Medicinal Products Act requires ManA for manufacture of API in Estonia. § 16 subsection (3)***

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

*(1) The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC, shall also be required for imports coming from third countries into a Member State.*

*(2) Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

*(3) These requirements fulfil the GMP recommendations of WHO. <http://eudragmp.ema.europa.eu>. If it does not appear, please contact the issuing authority.*

## Part 2

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

***OXYGEN(en)***

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance: OXYGEN

<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	3.2.7 Other: Liquid oxygen, by air separation
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing

2023-07-18

Name and signature of the authorised person  
of the competent authority of Estonia



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