



## State Office of Health and Social Affairs Berlin

### MANUFACTURER'S AUTHORISATION

Authorisation number/reference number  
5373/1-Biochrom/3

Name of authorisation holder  
**Biochrom AG**

Address of manufacturing site  
**Leonorenstraße 2 - 6**  
**12247 Berlin**  
according to site plans no.1-9 as of December 18<sup>th</sup>, 2008

Legally registered address of authorisation holder  
**Leonorenstraße 2 - 6**  
**12247 Berlin**

Scope of authorisation and dosage forms  
see **annexes 1 and 4**

Legal basis of authorisation  
**section 13, sub-section 1 of the current version of the German Drug Law (Medicinal Products Act, Arzneimittelgesetz - AMG)**

Name of responsible officer of the competent authority of the member state granting the authorisation

**Wilke**

**State Office of Health and Social Affairs Berlin**  
Department I B  
P.O. Box 310929  
10639 Berlin

Signature

*[Signature: Wilke]*



Date  
**Berlin, September 23<sup>rd</sup>, 2011**

Annexes attached: Annex 1 - Authorisation scope  
Annex 4 - Contract laboratories in accordance with section 14, sub-section 4,  
no. 3 AMG

Note: Numbering complies with EMEA formatting guidelines.



## ANNEX 1

### SCOPE OF AUTHORISATION

Name and address of the manufacturing site:

**Biochrom AG**  
**Leonorenstraße 2 - 6**  
**12247 Berlin**

<input checked="" type="checkbox"/> Human Medicinal Products <input type="checkbox"/> Veterinary Medicinal Products
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### AUTHORISED MANUFACTURING OPERATIONS FOR MARKETED MEDICINAL PRODUCTS

<b>1.1</b>	<b>Sterile products</b>
	1.1.1 aseptically prepared
	1.1.1.1 large volume liquids
<b>1.6</b>	<b>Quality control testing</b>
	1.6.1 microbiological: sterility
	1.6.3 chemical/physical
	1.6.4 biological: bacterial endotoxins (LAL test)

Any restrictions or clarifying remarks related to the scope of these manufacturing operations

re 1.1	only solutions intended for the storage of organs, tissue or cells, as well as sodium chloride solution 25% (w/v).
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**ANNEX 4**

**CONTRACT LABORATORIES IN ACCORDANCE WITH SECT 14, SUB-SECT 4, NO. 3 AMG**

<b>Contract laboratory</b>	<b>Type of tests</b>
<b>LAT GmbH</b> <b>Dr. Tittel</b> Am Haag 4 82166 Gräfelfing	quality and quantity tests for anions and cations by means of: <ul style="list-style-type: none"><li>• HPLC</li><li>• atomic absorption spectroscopy (AAS)</li><li>• atomic emission spectroscopy (AES)</li></ul>
<b>Institut Kuhlmann GmbH</b> Analytik-Zentrum Ludwigshafen Hedwig-Laudien-Ring 3 67071 Ludwigshafen	<ul style="list-style-type: none"><li>• quantitative amino acid analysis using an amino acid analyser</li></ul>
<b>Labor L + S AG</b> Mangelsfeld 4 97708 Bad Bocklet-Großenbrach	quality and quantity tests for anions and cations by means of: <ul style="list-style-type: none"><li>• HPLC</li><li>• gas chromatography (GC)</li></ul> <ul style="list-style-type: none"><li>• tests for invisible particles / particle contamination by means of light blocking</li></ul> <ul style="list-style-type: none"><li>• tests for pyrogens (rabbit pyrogen test)</li></ul>

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