MANUFACTURER'S AUTHORISATION
(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number
   DE_NI_01_MIA_2018_0020/41401.01.09

2. Name of authorisation holder
   Fraunhofer Institut für Toxikologie und Experimentelle Medizin

3. Address(es) of manufacturing site(s)
   Fraunhofer Institut für Toxikologie und Experimentelle Medizin, Bereich Pharmazeutische Biotechnologie
   Inhoffenstr. 7
   38124 Braunschweig

4. Legally registered address of authorisation holder
   Nikolai-Fuchs-Str. 1
   30625 Hannover

5. Scope of authorisation and dosage forms
   ANNEX 2
   Sect 13 para 1 and sect 72 para 1 Arzneimittelgesetz (German Drug Law)

6. Legal basis of authorisation
   Dr. Susanne Weber

7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation
   On behalf

8. Signature

9. Date
   20/08/2018

10. Annexes attached
    Annex 2
    Annex 4 (Addresses of Contract Laboratories)
    Annex 8 (Manufactured/ imported products authorised)
**PART OF AUTHORISATION**

Investigational Medicinal Products for Human Use

**AUTHORISED OPERATIONS**
Manufacturing Operations (according to part 1)
Importation of Investigational Medicinal Products (according to part 2)

### Part 1 - MANUFACTURING OPERATIONS

<table>
<thead>
<tr>
<th>1.1 Sterile Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</td>
</tr>
<tr>
<td>1.1.1.4 Small volume liquids</td>
</tr>
<tr>
<td>1.1.2 Terminally sterilised (processing operations for the following dosage forms)</td>
</tr>
<tr>
<td>1.1.2.3 Small volume liquids</td>
</tr>
<tr>
<td>1.1.3 Batch certification</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.3 Biological medicinal products</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3.1 Biological medicinal products</td>
</tr>
<tr>
<td>1.3.1.5 Biotechnology products</td>
</tr>
<tr>
<td>1.3.2 Batch certification</td>
</tr>
<tr>
<td>1.3.2.5 Biotechnology products</td>
</tr>
</tbody>
</table>

**1.4 Other products or manufacturing activity**

<table>
<thead>
<tr>
<th>1.4.1 Manufacture of:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4.1.3 Other</td>
</tr>
<tr>
<td>- active pharmaceutical ingredients of genetically modified microbial and animal cells</td>
</tr>
<tr>
<td>- provocation substances</td>
</tr>
</tbody>
</table>

**1.5 Packaging**

<table>
<thead>
<tr>
<th>1.5.1 Primary Packing</th>
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</thead>
<tbody>
<tr>
<td>1.5.1.6 Liquids for internal use</td>
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</table>

| 1.5.2 Secondary packing |

**1.6 Quality control testing**
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<th>1.6.2</th>
<th>Microbiological: non-sterility</th>
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<tbody>
<tr>
<td>1.6.3</td>
<td>Chemical/Physical</td>
</tr>
<tr>
<td>1.6.4</td>
<td>Biological</td>
</tr>
</tbody>
</table>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations
Ad 1.1.2.3: [Redacted]
Products according to Annex 8
### Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

#### 2.2 Batch certification of imported investigational medicinal products

<table>
<thead>
<tr>
<th>2.2.1 Sterile products</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2.1.1 Aseptically prepared</td>
</tr>
</tbody>
</table>

#### 2.3 Other importation activities

<table>
<thead>
<tr>
<th>2.3.4 Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>provocation substances</td>
</tr>
</tbody>
</table>

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

Products according to Annex 8
Address(es) of Contract Laboratories

A & M Labor für Analytik und Metabolismusforschung Service GmbH
Kopernikusstr. 25
50126 Bergheim
- Peptide mapping Ph.Eur. 2.2.55

Eurosequence B.V. Meditech Center
L.J. Zielstraweg 1
NL-9713 GX Groningen
Niederlande
- N-terminal protein sequencing

L+S AG (Gesellschaft für Mikrobiologie und biologische Qualitätsprüfung)
Mangelsfeld 4
97708 Bad Bocklet-Großenbrach
- chemical/physical testing
- microbiological testing: sterility
- biological testing
- testing of pharmaceutical Technology
- leakage test (according Ph.Eur. 3.2.9)
- efficacy of antimicrobial preservation (Ph.Eur. 5.1.3)

Allergon AB
Välingevägen 309
26292 Angelholm
Schweden
- Identity, purity and content of pollen

Protagen Protein Services GmbH
Inselwiesenstr. 10
74076 Heilbronn
- RP-HPLC of proteins

GEMoAB Monoclonals GmbH
Tatzberg 47
01307 Dresden
- Potency and identity assay of
- Potency and identity Assay of

BioChem Labor für biologische und chemische Analytik GmbH
Daimlerstr. 5b
76185 Karlsruhe
- Assay of
- potency assay of
Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 45 and 46 of Directive 2001/82/EC, as amended).