IN VITRO DIAGNOSTIC PEPTIDES BACHEM
Our Center of Excellence for Custom Synthesis in St. Helens (UK) is certified according to ISO 13485 for the manufacture of peptides as critical raw materials for medical devices. It offers a state-of-the-art quality management system and peptide manufacturing equipment. Additional services such as the use of dedicated equipment during manufacturing and customized vialing of the finished product are available.
Regulatory requirements and standards in documentation and change control for in the in vitro diagnostic industry are constantly evolving. Bachem’s Research Grade Plus (RGP) service has been established for our customers with additional quality requirements that can be adapted «à la carte» to meet your specific needs (see table below).

**Benefits of the Bachem Research Grade Plus**
Research Grade Plus guarantees full traceability of critical raw materials throughout the whole supply chain, manufacturing according to an established and robust process, as well as batch-to-batch consistency for your peptides.

<table>
<thead>
<tr>
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<th>Research Grade</th>
<th>Research Grade Plus</th>
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<tbody>
<tr>
<td>Audits</td>
<td>✅*</td>
<td>✅</td>
</tr>
<tr>
<td>Critical Change Control</td>
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<td>✅</td>
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<tr>
<td>Master Production Record</td>
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<td>✅</td>
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<tr>
<td>Full Traceability of Critical Chemicals</td>
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<tr>
<td>TSE/BSE Certificate</td>
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<tr>
<td>Dedicated Equipment</td>
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<tr>
<td>Additional QC Specification Sheet</td>
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<tr>
<td>Customized Vials</td>
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<tr>
<td>Customized Peptide Mixture</td>
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<tr>
<td>Customized Shipment</td>
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*Possible under certain circumstances

**BACHEM SETS INDUSTRY STANDARDS FOR HIGH QUALITY CUSTOM PEPTIDES.**
Our high capacity and state-of-the-art production equipment are dedicated to yield your peptide in the quality and purity you require. Further, we offer you experienced technical support that will help you to identify the additional services that best suit your requirements.

Chemistry & Quality
- SPPS including a large selection of modifications
- State-of-the-art manufacturing & analytical capabilities

Dispensing
- Manual and fully automated dispensing capabilities
- Experienced in peptide mixture preparation

Capacity
- From mg up to 100g production scale
- Parallel production of multiple peptides

Support
- Stability study
- MDF (Medical Device File)
SUPPLY AND TECHNICAL AGREEMENTS

At Bachem, our priority is to build trustful, sustainable, and long-lasting relationships with our partners.

Bachem is a leading, innovation-driven company specializing in the development and manufacture of peptides and oligonucleotides. With 50 years of experience and expertise Bachem provides products for research, clinical development and commercial application to pharmaceutical and biotechnology companies worldwide and offers a comprehensive range of services. Bachem operates internationally with headquarters in Switzerland and locations in Europe, the US and Asia. The company is listed on the SIX Swiss Exchange. For further information, see www.bachem.com.
Bachem facilities are located in Switzerland, the EU, and in the USA.

All cGMP manufacturing sites are inspected by the US-FDA and national authorities.

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