



## Service Level Agreement (SLA) – Terms of Service – Aligned Elements as Hosted Solution

### Scope of Application and Conclusion of Contract

These general terms and conditions (“**Terms**”) shall be applicable to the relationship between you (“**Customer**” or “**You**”) and Aligned AG, Tellstrasse 31, 8004 Zürich, CHE--112.934.507 (“**Aligned**” or “**We**”) when You subscribe to, access or use the Aligned Elements Hosted Web Software (“**Aligned Elements Software**” or “**Service**”).

### Acceptance of Terms

By accessing or using the Aligned Elements Software, you agree and are bound of the terms in this Agreement. If you do not agree to the terms, please do not use the Aligned Elements Software.

### Service Description

The Service consists of an online software for creating and managing Design Control Documentation for medical devices, constituting web applications and databases hosted by Aligned AG. Not included are licenses for Microsoft Word.

### Service Commitment

Aligned AG will invest reasonable efforts to make the Aligned Elements Software available with a monthly uptime percentage of 99.9%, subject to the Aligned SLA exclusions.

A monthly uptime percentage of 99.9% means a maximum unavailability of 43 minutes / month.

### Service Extensions

Should a failure to meet the Service Level Commitment in a given month be confirmed, you can make a request for Service Extension. If received within thirty (30) days after the end of the given month, the requester will be entitled to a Service Extension of one (1) additional day for every 15 minutes of downtime.

Aligned service logs will be the source of truth in determining whether the uptime commitment has failed to be met.

The service extension is applied to your current subscription. No refunds or cash value will be given for unused service extensions. We reserve the right to deny any service extension if you do not qualify for one.

### SLA Exclusions

You will not be entitled to a Service Extensions if you breach the Terms of use Aligned Elements Software in an unauthorized manner according to the Terms.

The Service Level Commitment will not include unavailability due to force majeure events or other factors outside our reasonable control; including, without limitation to, Internet access, denial of service attacks or other access restrictive attacks, problems with your equipment, network connections, software or other infrastructure, abnormal use of the application via GUI, tools or API, routine scheduled maintenance or reasonable emergency maintenance or problems caused by add-ons or third parts equipment or software.

No Service Level Commitment is provided for free versions, proof-of-concept versions, beta versions or trial versions.

### User Account Security

You are responsible for keeping your Aligned Elements Software user account secure while you use the Service. You are responsible for maintaining the security of your account and password. Aligned cannot and will not be liable for any loss or damage from your failure to comply with this security obligation. You will promptly notify Aligned if you become aware of any unauthorized use of, or access to, our Service through your account, including any unauthorized use of your password or account.

### Physical and Operational Security

Infrastructure is hosted in Microsoft Azure data centers, compliant with key industry standards, including ISO/IEC 27001:2005. They are managed, monitored, and administered by Microsoft operations staff.

More information on Windows Azure security can be found here:

<https://azure.microsoft.com/en-gb/support/trust-center/>

### Network Security

Data in transit is encrypted with 256-bit SSL communication (HTTPS).

### Application Security

Tightly controlled network-level firewalling is applied.

IP restriction option is available where access is restricted to an IP specific range defined by the customer.

Users have to authenticate in order to access the Aligned Elements Software data.

### Data Security

Aligned does not scan content added into Aligned Elements Software projects for malware.

It is up to you to ensure that uploaded content is malware free.

Passwords are stored in an encrypted format in the Aligned Elements Software.

Apart from passwords, no data-in-rest is encrypted in order to ensure full text search capabilities.

### Data Isolation

All customer data is stored securely and kept confidential.

Single-tenant environment where customer data resides on unique, separated databases and file systems which prevents access to / from other customers.

## **Patching**

Patches to the Windows Server, SQL Server and IIS Server is done periodically every month.

## **Data Access**

Access to Aligned Elements data in Microsoft Azure data centers is strictly controlled and monitored by Microsoft staff.

## **Specifications on Infrastructure**

Windows Server 2016 or higher

SQL Server 2017 Web Edition or higher.

## **Backup policy**

SQL databases are backed up to cloud every 24 hours with a retention time 30 days.

Virtual Machines are backed up weekly with a retention 60 days.

## **Intellectual Property Rights / Data Ownership**

We respect your right to ownership of content created or stored by you in the Aligned Elements Software. You own the content created and stored by you. Unless specifically permitted by you, your use of the Aligned Elements software does not grant Aligned AG the license to use, publish or distribute your content. However, you grant Aligned AG permission to access, copy, distribute, store, transmit and reformat the content to your user account as required for the purpose of providing the Aligned Elements Software to you.

You are solely responsible for content created by you using the Aligned Elements Software and you assume all risk associated with the use of your content including, but not limited to, the accuracy, integrity and quality of that content.

By adding and storing content in the Aligned Element Software, you warrant that you own or otherwise control the intellectual property rights or other rights to that content. Further, you expressly agree that Aligned AG will have the right to block access or remove such content if Aligned AG receives complaints concerning any illegality or infringement of third party rights in such content.

As a user, you acknowledge that Aligned AG has no liability should a party that you grant access to your content copy, distribute, modify, destroy or corrupt or violate the terms of use or other limitations that you impose on the use of your data. Aligned AG remains the owner of all intellectual property rights to the Aligned Element Software as well as in any logos, trademarks or online editorial materials of Aligned AG.

Save to the extent expressly permitted by this Agreement or required by mandatory law, any use of the Aligned Elements Software shall be subject to the following limitations:

You may not use or alter the Aligned AG brand;

You may not decompile or reverse engineer the Aligned Element Software (or the source code of any other third party involved and accessible under the Services), unless permitted under mandatory applicable law.

## **Fees and Payments**

The yearly fees for the Aligned Element Software are to be paid as per instructions from Aligned AG.

If you do not wish to renew the subscription, you must notify us at least seven (7) business days prior to renewal date.

In the event a customer should not pay the fee in time for the period covered in the subscription, Aligned AG will have the right to suspend the service until the fee is paid.

## **Termination**

Aligned AG may suspend the customer access to the service if:

- a) The Customer has breached the terms of this agreement or
- b) Customer fails to pay any amount after 20 days after their due date

If suspended, Aligned AG will promptly restore customer's services after the event giving rise to the suspension has been resolved to Aligned AG's reasonable satisfaction.

Either Party may terminate this Agreement with a sixty (60) days prior notice (termination for convenience).

Upon termination of the Agreement, Aligned AG will retain the customers content for thirty (30) days maximum. Aligned AG will inform the Customer (e-mail sufficient) that, after expiry of the thirty (30) days, the Customers content will be deleted. It is Subscriber's responsibility to secure Subscriber's content in its own organization.

## **Disclaimer of Warranties**

Aligned Elements Software is provided under these terms of use "as is" without warranty of any kind. To the maximum extent possible under the applicable law, Aligned excludes any and all representations and warranties, whether implied or explicit, with regard to the subject matter of the Terms in this Agreement.

## **Limitation of Liability**

You acknowledge that you use the Aligned Elements Software for your own business purposes and at your own risk. Aligned assumes no, and hereby excludes any and all, responsibility for suitability of the Services for the purposes envisaged by you. To the extent possible under the applicable laws, Aligned AG hereby excludes any and all liabilities arising under this Agreement or relating to the subject matter of this Agreement (including liability claims arising under contract or tort). In particular, Aligned AG shall not be liable with respect to any direct, or indirect, or special, consequential damages such as loss of profits particularly arising from the use of data, use of Intellectual Property or the non-availability of the Services or loss of data.

## **Release and Indemnification**

If you have a dispute, you agree to release Aligned AG from any and all claims, demands and damages (actual and consequential) of every kind and nature, known and unknown, arising out of or in any way connected with such disputes. You agree to indemnify us, defend us, and hold us harmless from and against any and all claims, liabilities, and expenses, including attorneys' fees, arising out of your use of the Aligned Elements Software, including but not limited to your violation of this Agreement, provided that Aligned AG (1) promptly gives you written notice of the claim, demand, suit or proceeding; (2) gives you sole control of the defence and settlement of the claim, demand, suit or proceeding (provided that you may not settle any claim, demand, suit or proceeding unless the settlement unconditionally releases Aligned AG of all liability); and (3) provides to you all reasonable assistance, at your expense

**Governing Law and Jurisdiction**

This Agreement shall be governed by the substantive laws of Switzerland without any reference to conflict of law rules. The exclusive place of jurisdiction for all disputes arising from or in connection with this Agreement shall be the city of Zurich, Switzerland. Nothing in this clause shall refrain or limit Aligned AG from enforcing its rights before any other competent courts in Switzerland or abroad (in particular, but not limited to seeking preliminary injunctive relief or similar enforcement actions).

**Miscellaneous**

We may modify these Terms upon notice to you at any time by contacting you via email to your primary email address. If we make significant changes to the Terms that affect your rights, you will be notified at least 30 days in advance.