

Verification of Declaration of Adherence

Declaring Company: Extra Horizon N.V.



EU
CLOUD
COC

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1 Verification against v2.11 of the EU Cloud CoC

This Declaration of Adherence was against the *European Data Protection Code of Conduct for Cloud Service Providers* (**'EU Cloud CoC'**)¹ in its version 2.11 (**'v2.11'**)² as of December 2020.

Originally drafted by the Cloud Select Industry Group³ (**'C-SIG'**) the EU Cloud CoC – at that time called C-SIG Code of Conduct on data protection for Cloud Service Providers – was developed against Directive 95/46/EC⁴ and incorporated feedback by the European Commission as well as Working Party 29. Following an extensive revision of earlier versions of Code and further developing the substance of the Code (v2.11) and its provisions has been aligned to the European General Data Protection Regulation (**'GDPR'**)⁵.

2 List of declared services

2.1 Extra Horizon⁶

Extra Horizon provides a Medical Backend as a Service (MBAAS), allowing customers to build medical software applications in the cloud on infrastructure that is regulatory compliant with IEC 62304. The customer can select several services from the Extra Horizon services family that will be deployed in a dedicated infrastructure.⁷

- User Service
- Authentication Service
- File Service
- Data Service
- Task Service
- Notification Service
- Template Service
- Event Service
- Mail Service
- Localisation Service
- Payment Service+
- SMS Service
- Configuration Service
- Dispatcher Service

¹ <https://eucoc.cloud>

² <https://eucoc.cloud/get-the-code>

³ <https://ec.europa.eu/digital-single-market/en/cloud-select-industry-group-code-conduct>

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31995L0046>

⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679>

⁶ <https://www.extrahorizon.com/>

⁷ **NOTE:** The content for the service description has been provided by the CSP and does not reflect any opinion of or assessment by the Monitoring Body.

3 Verification Process - Background

V2.11 of the EU Cloud CoC has been developed against GDPR and hence provides mechanisms as required by Articles 40 and 41 GDPR⁸.

3.1 Approval of the Code and Accreditation of the Monitoring Body

The services concerned passed the verification process by the Monitoring Body of the EU Cloud CoC, i.e., SCOPE Europe sprl/bvba⁹.

The Code has been officially approved in May 2021¹⁰. SCOPE Europe has been officially accredited as Monitoring Body in May 2021¹¹. The robust and complex procedures and mechanisms can be reviewed by any third-party in detail at the website of the EU Cloud CoC alongside a short summary thereof.¹²

3.2 Principles of the Verification Process

Notwithstanding the powers of and requirements set out by the supervisory authority pursuant to Article 41 GDPR, the Monitoring Body will assess whether a Cloud Service, that has been declared adherent to the Code, is compliant with the requirements of the Code - especially as laid down in the Controls Catalogue. Unless otherwise provided by the Code, the Monitoring Body's assessment process will be based on an evidence-based conformity assessment, based on interviews and document reviews; proactively performed by the Monitoring Body.

To the extent the Monitoring Body is not satisfied with the evidence provided by a CSP with regards to the Cloud Service to be declared adherent to the Code, the Monitoring Body will request additional information. Where the information provided by the CSP appears to be inconsistent or false, the Monitoring Body will - as necessary - request substantiation by independent reports.

3.3 Multiple Safeguards of Compliance

Compliance of adherent services is safeguarded by the interaction of several mechanisms, i.e., continuous, rigorous, and independent monitoring, an independent complaints' handling process, and

⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679>

⁹ <https://scope-europe.eu>

¹⁰ <https://www.gegevensbeschermingsautoriteit.be/publications/decision-n05-2021-of-20-may-2021.pdf>

¹¹ <https://www.gegevensbeschermingsautoriteit.be/publications/decision-n-06-2021-of-20-may-2021.pdf>

¹² <https://eucoc.cloud/en/public-register/assessment-procedure/>

finally any CSP declaring services adherent is subject to substantial remedies and penalties in case of any infringement.

3.4 Process in Detail

It is expected that, prior to any assessment of the Monitoring Body, each CSP assesses its compliance internally. When declaring its service(s) adherent to the EU Cloud CoC, each CSP must elaborate its compliance with each of the Controls as provided by the Code considering the Control Guidance, as provided by the Controls Catalogue, to the Monitoring Body.

The CSP may do so either by referencing existing third-party audits or certifications, their respective reports and by free text responses. Additionally, the CSP will have to provide a general overview of the functionalities, technical, organisational and contractual frameworks of the service(s) declared adherent.

With regards to internationally recognised standards, the Monitoring Body will consider the mapping as provided by the Controls Catalogue. However, the Monitoring Body will verify whether (a) any third-party certification or audit provided by the CSP applies to the Cloud Service concerned, (b) such third-party certification or audit provided by the CSP is valid, (c) such third-party certification or audit has assessed and sufficiently reported compliance with the mapped controls of the third-party certification or audit concerned. Provided that the aforementioned criteria are met, the Monitoring Body may consider such third-party certifications or audits as sufficient evidence for the compliance with the Code.

Within Initial Assessments, the Monitoring Body selects an appropriate share of Controls that will undergo in-depth scrutiny, e.g., by sample-taking and requesting further, detailed information including potentially confidential information. Within any other Recurring Assessment, the Monitoring Body will select an appropriate share of Controls provided that over a due period every Control will be subject to scrutiny by the Monitoring Body. Where applicable, aspects of current attention at the time of assessment shall be covered too, e.g., where such aspects were indicated in media reports, publications or actions of supervisory authorities.

If the responses of the CSP satisfy the Monitoring Body, especially if responses are consistent and of appropriate quality and level of detail, reflecting the requirements of the Controls and indicating appropriate implementation by the Control Guidance, then, the Monitoring Body verifies the service(s) declared adhered as compliant and thereupon, makes them subject to continuous monitoring.

3.4.1 Levels of Compliance

V2.11 of the Code provides three different levels of Compliance. The different levels of compliance relate only to the levels of evidence that are submitted to the Monitoring Body. There is, however, no difference in terms of which parts of the Code are covered, since adherent Cloud Services have to comply with all provisions of the Code and their respective Controls.

3.4.1.1 First Level of Compliance

The CSP has performed an internal review and documented its implemented measures proving compliance with the requirements of the Code with regard to the declared Cloud Service and confirms that the Cloud Service fully complies with the requirements set out in this Code and further specified in the Controls Catalogue. The Monitoring Body verifies that the Cloud Service complies with the Code by information originating from the CSP.

3.4.1.2 Second Level of Compliance

Additional to the “First Level of Compliance”, Compliance with the Code is partially supported by independent third-party certificates and audits, which the CSP has undergone with specific relevance to the Cloud Service declared adherent and which were based upon internationally recognised standards procedures. Any such third-party certificates and audits that covered controls similar to this Code, but not less protective, are considered in the verification process of the Monitoring Body. Each third-party certificates and audits that were considered in the verification process by the Monitoring Body shall be referred in the Monitoring Body’s report of verification, provided that the findings of such certificates were sufficiently and convincingly reported and documented towards the Monitoring Body and only to the extent such certificates and audits are in line with the Code. The CSP must notify the Monitoring Body if there are any changes to the provided certificates or audits.

The Controls Catalogue may give guidance on third-party certificates and audits that are equivalent to certain Controls in terms of providing evidence of complying with the Code.

However, to those Controls that the CSP has not provided any equivalent third-party certificate or audit, the Monitoring Body verifies that the Cloud Service complies with the Code by information originating from the CSP.

The Monitoring Body may refuse application of Second Level of Compliance if third-party certificates and audit reports, that are recognised by the Monitoring Body in the verification process concerned, are not covering an adequate share of Controls of this Code; such adequate share shall be subject to the discretion of the Monitoring Body, considering e.g., the share related to the overall amount of Controls of the Code or whether a full Section or topic is being covered.

3.4.1.3 Third Level of Compliance

Identical to the “Second Level of Compliance” but Compliance is fully supported by independent third-party certificates and audits, which the CSP has undergone with regard to the Cloud Service declared adherent and which were based upon internationally recognised standards.

To the extent a CSP refers to individual reports, such as ISAE-3000 reports, the CSP shall ensure that such reports provide sufficient and assessable information and details on the actual measures implemented by the CSP regarding the Cloud Service concerned. The Monitoring Body shall, if considered necessary, in consultation with the Steering Board, define further requirements on such individual reports, such as accreditation and training for auditors against the provisions and requirements of this Code.

3.4.2 Final decision on the applicable Level of Compliance

When declaring its Cloud Service adherent, the CSP indicates the Level of Compliance it is seeking to achieve. Any final decision, whether a CSP is meeting the requirements of a specific Level of Compliance is at the sole discretion of the Monitoring Body.

3.5 Transparency about adherence

Each service adherent to the EU Cloud CoC must transparently communicate its adherence by both using the appropriate Compliance Mark¹³ and referring to the Public Register of the EU Cloud CoC¹⁴ to enable Customers to verify the validity of adherence.

4 Assessment of declared services by Extra Horizon (see 2.)

4.1 Fact Finding

Following the declaration of adherence of Extra Horizon N.V. (**‘Extra Horizon’**), the Monitoring Body provided Extra Horizon with a template, requesting Extra Horizon to detail its compliance with each of the Controls of the EU Cloud CoC.

As this declaration is a renewal¹⁵, the Monitoring Body requested from Extra Horizon a confirmation that there has been no material change to the applicable technical and organisational and contractual framework. The Monitoring Body also requested from Extra Horizon a comparison of the declared Cloud Services of last year and this year as well as to explicitly indicate any Cloud Services that are

¹³ <https://eucoc.cloud/en/public-register/levels-of-compliance/>

¹⁴ <https://eucoc.cloud/en/public-register/>

¹⁵ You can access the Verification Report(s) of previous year(s) via the following link(s): [Verification Report 2021](#)

no longer included in the Declaration of Adherence and, where applicable, provide the Monitoring Body with adequate reasons. To the extent the list of Cloud Services was extended, the Monitoring Body requested a confirmation, that any such additional Cloud Services are subject to the same technical, organisational and contractual framework as the original Cloud Services.

Extra Horizon promptly responded to the templates. Information provided consisted of references and list of actual measures meeting the requirements of each Control, a free text answer describing their measures, and a reference to third party audits and certifications, where applicable. This information was completed by the two confirmations requested by the Monitoring Body as well as a detailed comparison of the declared Cloud Services between last year and this year verification highlighting the changes and the reasons for them.

4.2 Selection of Controls for in-depth assessment

Following the provisions of the Code and the Assessment Procedure applicable to the EU Cloud CoC¹⁶, the Monitoring Body analysed the responses and information provided by Extra Horizon.

Extra Horizon's declared services have been externally certified and audited. Extra Horizon holds, besides others, ISO 27001:2017 and ISO 27701:2019 certificates, which are valid for the duration of the Declaration of Adherence, and the scope of registration includes all the declared services. The declaration of adherence referred to the relevant ISO certifications within the responses to Section 6 of the Code (IT Security). As provided by the Code, the Monitoring Body may consider third-party certifications and audits. Accordingly, the Monitoring Body verified the certification and references. Further in-depth checks were not performed, as provided third-party certifications adequately indicated compliance.

4.3 Examined Controls and related findings by the Monitoring Body

4.3.1 Examined Controls

The Monitoring Body reviewed the submission from Extra Horizon which outlined how all the requirements of the Code were met by Extra Horizon's implemented measures. In line with the Monitoring Body's process outlined in Section 3.4, the Monitoring Body selected a subset of Controls from the Code for in-depth scrutiny. In-depth scrutiny reflects sample taking and follow-up questions, whilst the latter may address requests for clarifications or more detailed information. The Controls selected for

¹⁶ <https://eucooc.cloud/en/about/about-eu-cloud-coc/applicable-procedures/>

this level of review were: 5.1.A, 5.1.D, 5.1.E, 5.2.B, 5.2.C, 5.3.A-B, 5.3.D, 5.3.F, 5.4.A-C, 5.4.E, 5.5.E, 5.7.A-B, 5.8.A-B, 5.10.A-B, 5.11.A-C, 5.12.F, 5.14.A, 5.14.E-F and 6.1.A.

4.3.2 Findings by the Monitoring Body

During the process of verification, Extra Horizon consistently prepared the Declaration of Adherence well and thoroughly. Extra Horizon's responses were detailed and never created any impression of intentional non-transparency. Requests for clarification, additional and supporting information, as well as relevant samples were promptly dealt with and always met the deadlines set by the Monitoring Body.

Related to the Monitoring Body's requests (see section 4.1), Extra Horizon indicated that no relevant changes to the Cloud Service Family were applied in regards of the implemented technical, organisational and contractual framework.

One areas of assessment has been the enablement of Customers, with respect to Customers accessing all relevant information, deletion of Customer Personal Data, as well as responding to Data Subjects Requests. Customers are provided with the possibility to do so through self-service functionalities. Extra Horizon confirmed that where Customers may need more information not covered by the self-service functionalities provided, Customers may send specific work orders to Extra Horizon to enable the latter to support and assist Customers.

Another area of focus was built around subprocessor management. Extra Horizon has a defined mechanism to notify Customers of the changes in subprocessors. The timelines for objection and/or exercising an alternative option, as well as the means to do so were confirmed by Extra Horizon 's contractual documents. The good standing of subprocessors, as well as the technical and organisational measures implemented by them are verified by Extra Horizon. In the same vein, flow-down mechanisms are implemented and this includes contractual obligations of subprocessors to adhere to the same standards of data processing as the Extra Horizon. In that respect, Extra Horizon maintains an internal register as a means to ensure that the requirements of internal subprocessing procedures originating from agreements will be met.

Regarding the third country transfers, Extra Horizon implemented safeguards as provided by Chapter V GDPR. Extra Horizon has implemented the new Standard Contractual Clauses (SCCs), which are used as a transfer mechanism and Extra Horizon's agreements have been updated accordingly.

Extra Horizon's records of processing ("ROPA") built another area of focus. Based on the information provided, Extra Horizon maintains a ROPA in its capacity as Processor, which includes all relevant

information required under Art 30.2 GDPR. The relevant communication channels for Customers to provide the relevant information in relation to the completion and relevancy of the ROPA were confirmed by Extra Horizon.

Procedures to deal with requests from Supervisory Authorities were assessed. Extra Horizon has an internal procedure to deal with requests from data protection Supervisory Authorities, which describes how potential requests from Supervisory Authorities are handled and recorded, and includes direct and indirect requests.

The Monitoring Body assessed Extra Horizon's policies related to data retention and disposal which establishes the requirements for return, transfer or disposal of Customer Data, including Personal Data. Extra Horizon's policies provide an overview on the means for data retrieval, as well as specific procedures for data disposal and wiping.

5 Conclusion

The information provided by Extra Horizon were consistent. Where necessary, Extra Horizon gave additional information or clarified their given information appropriately.

The Monitoring Body therefore verifies the services as compliant with the EU Cloud CoC based on the performed assessment as prescribed in 1. The service(s) will be listed in the Public Register of the EU Cloud CoC¹⁷ alongside this report.

In accordance with sections 3.4.1.2 and 3.4.2 and given the type of information provided by Extra Horizon to support the compliance of its service, the Monitoring Body grants Extra Horizon with a Second Level of Compliance.

6 Validity

This verification is valid for one year. The full report consists of 10 pages in total, whereof this is the last page closing with the Verification-ID. Please refer to the table of contents at the top of this report to verify that the copy you are reading is complete, if you have not received the copy of this report via the Public Register of the EU Cloud CoC¹⁸.

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¹⁷ <https://eucooc.cloud/en/public-register/>

¹⁸ <https://eucooc.cloud/en/public-register/>