SCOPE EUROPE

Verification of Declaration of Adherence

Declaring Company: Extra Horizon N.V.

Verification-ID	2021LVL02SCOPE318
Date of Approval	December 2023
Valid until	December 2024

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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 Group[3] (**'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/EC[4] 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 Horizon[6]

The Extra Horizon platform is composed of a set of services intended for cloud connected medical devices. The Extra Horizon services together act as a backend as a service for your medical device.[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

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 GDPR[8].

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

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/bvba[9].

The Code has been officially approved in May 2021[10]. SCOPE Europe has been officially accredited as Monitoring Body in May 2021[11]. 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 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

[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/

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 Mark[13] and referring to the Public Register of the EU Cloud CoC[14] 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 renewal[15], 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 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

[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): Extra Horizon Verification Report (2022)

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 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 CoC[16], 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 an ISO 27001 and ISO 27701 certificates, which is 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 respective ISO 27001 certification 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 this level of review were: 5.1.B-E, 5.2.C-D, 5.3.A-B, 5.3.E, 5.4.A, 5.4.C, 5.5.A, 5.7.A-B, 5.7.E-F, 5.8.A-B, 5.9.B, 5.10.A, 5.11.A-B, 5.12.C-D, 5.12.F, 5.13.A, 5.14.E-F, 6.1.B-D, 6.2.H and 6.2.P.

[16] https://eucoc.cloud/en/about/about-eu-cloud-coc/applicable-procedures/

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. Where additional Cloud Services were added, Extra Horizon provided explicit confirmation that such Cloud Services belong to the same Cloud Service Family.

The Monitoring Body has focused on the assistance and information provided to the Customers. Based on the information provided by Extra Horizon, adherence to the Code is transparently communicated to the Customers and relevant contractual documents are in place, addressing among other responsibilities of the CSP and Customers. Extra Horizon has indicated that Customers are provided with various self-service capabilities to deal autonomously with the data subject requests including deletion, retrieval and export of the Customer Personal Data.

In this vein, Customers are provided with supporting documentation about the provided services and its functionalities. Extra Horizon has attested that it provides Customers with information on the technical and organisational measures (TOMs) and third-party attestations, if available. Additionally, Customers are provided with the Data Protection Point of Contact information and may reach out for additional assistance via a dedicated communication channel.

Further, the Monitoring Body has assessed Extra Horizon's Records of Processing Activities (ROPA). The Monitoring Body was able to confirm as per information provided by Extra Horizon that it maintains a ROPA in its capacity as Processor, which includes the relevant information as per Article 30.2 GDPR. Dedicated communication channels are made available to the Customers by Extra Horizon to provide and update the information pertaining to the completion and relevance of a ROPA.

Another area of assessment has been data breach notification and reporting obligations. Extra Horizon has identified that relevant security and incident management procedures are in place, allowing for the identification and further reporting of data breaches as required by the Code and GDPR. Extra Horizon's data breach notification and reporting obligations are included as a standard part of the contractual documents with Customers.

Confidentiality obligations alongside with the training and awareness obligations with regards to the employees and contractors were also part of the assessment. Extra Horizon has confirmed that confidentiality obligations are in place with employees and contractors, which continue after the end of the respective agreements. In this regard, employees and contractors are provided with obligatory awareness, privacy and security trainings on a regular basis as stipulated by the internal policies and procedures. Such trainings are subject to regular reviews and are specific as to the role and functions of the personnel.

On the other hand, Extra Horizon confirmed to ensure that relevant policies and procedures are in place to enable its personnel to adequately deal with Customer inquiries and to make sure that Customer Personal Data is not processed by any personnel for any purpose independent of the Instructions of the Customer. Additionally, it has been indicated by Extra Horizon that Customer instructions and their scope are included and defined in the contractual documents with the Customers.

Third country transfers have also been part of the assessment. Extra Horizon indicated that it relies on the appropriate data transfer safeguards as provided by Chapter V GDPR, such as adequacy decisions, Standard Contractual Clauses (SCCs) and Binding Corporate Rules (BCRs).

Finally, Extra Horizon's media disposal and data wiping procedures have been assessed. The relevant data disposal and wiping procedures have been confirmed to be in place by Extra Horizon, ensuring that Customer Personal Data is disposed accordingly, by rendering such data and related software unreadable.

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 CoC[17] alongside this report.

[17] https://eucoc.cloud/en/public-register/

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 11 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 CoC[18].

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[18] https://eucoc.cloud/en/public-register/