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Title	**REGULATION FOR THE GRANTING AND THE MAINTAINING OF THE CERTIFICATION OF THE PRODUCT ERGONOMIC FEATURES**
Number	**D000-CEP**
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Approval	Implementation
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1. GENERAL DESCRIPTION

ErgoCert is a product certifying body, operating in compliance with the general requirements of UNI CEI EN ISO/IEC17065:2012 standard.
In accordance with paragraph 1 of UNI CEI EN ISO/IEC 17065 standard, "in this Regulation the term 'product' is used in the broadest sense and includes processes and services, ... omitted ..." except the cases in which this distinction is clearly evidenced.
In its activities, **ErgoCert** complies not only with the current regulatory requirements and voluntary standards, but also with the requirements of an internal quality system.
It does so not only in the perspective of professional deontology, but also to guarantee its clients the utmost transparency and a high level of reliability and trust.
For this reason, **ErgoCert** does not perform any consultancy activity in the product certification field – either directly or through associated companies.
It should be noted that by consultancy activity it is meant the participation in activities of designing, manufacturing, installing, servicing, or distributing a certified product or a product to be certified.

ErgoCert mainly performs the following activities:

- pre-audit, ergonomic expertise;
- certification audit;
- testing with users;
- training.

2. PURPOSE AND SCOPE

This Regulation defines the terms and conditions for the product certification pursuant to UNI CEI EN ISO/IEC 17065 standard. The term "product certification" indicates an assessment carried out by an impartial third party to certify that the tested products comply with specific requirements, generally found in international standards or in other regulatory instruments.
Thus, what can be certified are the ergonomic features of a product/process/service, for which **ErgoCert** has drawn up an Area Technical Regulation (Disciplinare Tecnico d'Area - DTA) and/or a Technical Specification (Specifica Tecnica – ST) to define the terms of application of the law to assess ergonomic compliance.
The impartiality in assessments and the nature of their operating processes are the conditions for the reliability of the assessment outcomes.
Precisely to assure the consumers, the manufacturers, and all the other interested parties that the assessments are reliable (and that the certified products are compliant, for instance from the point of view of usability, comfort, safety, performance, and that they have been manufactured in accordance with procedures that do not undermine such principles as fair competition), the body tasked with performing them has to comply with the aforementioned UNI CEI EN ISO/IEC 17065 standard.
This Regulation:

- defines the terms, the procedures, and all the other elements required for the product certifications carried out by **ErgoCert** to be compliant with UNI CEI EN ISO/IEC 17065:2012 standard.
- is applicable to the activities of product ergonomic certification in a voluntary and mandatory context.
- defines the relationship between **ErgoCert** – Ergonomics Certifying Body – and the companies that intend to obtain,

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and register, the voluntary certification of their products.

A Committee for Safeguarding Impartiality (Comitato di Salvaguardia della Imparzialità – CSI, see specific regulation D002-CEP) and a Certification Committee – appointed by ErgoCert's sole director - supervise the application of this Regulation, as defined in the ErgoCert Impartiality Policy (D014-SGQ).

To this end, **ErgoCert** identifies, analyzes and records possible conflicts of interest, including conflicts that may arise from its relationships.

ErgoCert means to show that it has taken the risks deriving from its certification activities into account, and has taken appropriate measures, such as insurance or reserves, to cover liabilities deriving from its activities in every field and geographical area in which it operates.

ErgoCert keeps its financial situation and its sources of revenue under control, showing to the Committee for Safeguarding Impartiality – both at the outset and later on – that pressure, commercial, financial or otherwise, does not compromise said impartiality. The tasks of the Committee for Safeguarding Impartiality are:

- to assist the body in the development of policies related to the impartiality of its certification activities;
- to contrast every tendency, on the part of the certifying body, to be affected by some aspects, commercial or otherwise, that prevent a congruent and objective performing of the certification activities;
- to provide suggestions on aspects that may affect trust in the certification, including transparency and public perception;
- to carry out a review, at least once a year, about the impartiality of audits, certifications, and decision-making processes of the certifying body.

3. APPLICABLE NORMATIVE DOCUMENTS AND REFERENCE DOCUMENTS

3.1 MAIN APPLICABLE NORMATIVE DOCUMENTS

In order to obtain the product/process/service certification above 1 star (polytechnical compliance and compliance with the general ergonomic requirements), it is necessary to draw up a Technical Specification to define:

The identification of the specific product/process/service
The certifiable ergonomic features
The applicable technical standards and the related implementing provisions
The ergonomic test methods and acceptable limits.

The normative documents used by **ErgoCert** to draw up the General Technical Regulation (Disciplinare Tecnico Generale - DTG), the Area Technical Regulations (Disciplinari Tecnici di Area – DTA), and the Technical Specifications (Specifiche Tecniche - ST) are issued by standardization bodies, governmental authorities, private associations, consortia or single bodies.

The normative documents constituting the basic references for this Regulation are those reported in the reference ACCREDIA document "LS-02 Elenco norme e documenti di riferimento per l'accreditamento degli Organismi di Certificazione" ("List of standards and reference documents for the accreditation of the certifying bodies" - www.accredia.it), only as regards the activities listed in paragraph 2 of this Regulation.

In addition, certification activities for the mandatory sector only are carried out in compliance with the applicable regulations and European directives, as implemented within Italian law.

Among these, there are also the reference documents issued by the ACCREDIA accreditation body (regulations, technical reports, circulars, etc.), in the version that may be applicable at the time of performing the activities; as a matter of fact, such documents

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contain additional provisions to the aforementioned standards, which are mandatory for **ErgoCert** as accredited certifying body. Any modifications in the normative framework and in the knowledge about ergonomics and usability require an update of the related ErgoCert normative documents.

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Below is a list of the main applicable normative documents:

ISO/IEC 17065:2012: Product certification

ACCREDIA RG 01: Regulation for the accreditation of the certification, inspection, verification, and validation bodies

ACCREDIA RG01-03: Regulation for the accreditation of the product/process/service certifying bodies

ACCREDIA RG 09: Use of the ACCREDIA brand

UNI CEI EN ISO/IEC 17067: Compliance assessment – Basic elements of product certification and guidelines for product certification schemes

ISO/IEC TR 17026: Compliance assessment – Example of a certification scheme for tangible products

UNI CEI EN ISO/IEC 17000: Vocabulary and general principles

GENERAL TECHNICAL REGULATION (DISCIPLINARE TECNICO GENERALE) – AREA TECHNICAL REGULATIONS (DISCIPLINARI TECNICI D'AREA - DTA) – ERGOCERT TECHNICAL SPECIFICATIONS (SPECIFICHE TECNICHE - ST): Reference documents for ergonomic certification - Requirements

FURTHER ERGONOMICALLY RELEVANT NORMATIVE REQUIREMENTS

3.2 REQUIREMENTS FOR THE APPLICANT ORGANIZATION

The certification is granted only if the applicant carries out and maintains the production/supply process of the product/pro cess or service according to documented methods, using proper means in order to guarantee the constant compliance of the product/process/service with the specified requirements.

About the products deriving from production processes, the certification may be requested by:

- The producer or manufacturer of said product, that is, an organization that carries out or checks the various stages of the production process, such as the design, proper manufacturing, verification, storing, etc. of a given product, thus taking ful l responsibility for the compliance of the product with the requirements to certify.
- An organization having with the producer or manufacturer a specific agreement, legally usable, guaranteeing that **ErgoCert** has no less monitoring and control on the production processes than the manufacturers themselves.

4. DEFINITIONS

Audit-Assessment: activity through which **ErgoCert** ensures that the applicant company works in compliance with what is stated in the technical regulation, technical specifications, and reference standards.

Audit report: the audit report is a document that records the results of the ergonomic compliance assessment deriving from the audit activities.

Certification Committee: committee that examines the documents after the inspection checking and ap proves the granting, or not, of the certificate of compliance.

Certification specification: document about families of specified products, to which the same requirements specified by the applicable standards apply.

Certified European Ergonomist – EUR ERG Certification: the Eur.Erg title is conferred and allows its certified recipients to work as ergonomists with the endorsement of IEA in the 47 countries where there are federated companies. The Centre for the

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Registration of the European Ergonomists (CREE) is the professional certifying body supported by European ergonomics associations and recognized by the International Ergonomics Association (IEA).

Certifying body: body that carries out the certification of compliance.

Company: organization that supplies a product or service, linked to **ErgoCert** by agreements involving the compliance with the requirements set out in the Regulation.

ErgoCert certification requirement: specified requirement, including the product requirements, fulfilled by the client as a condition to issue or maintain the ergonomic certification.

ErgoCert Assessor-Auditor: person with the skills and the qualification to carry out audits to check ergonomic compliance; such qualification may be attested only by **ErgoCert**. The terms “assessor-auditor” and “inspector” are to be considered as equivalent.

Ergonomic expertise: assessment by an expert in ergonomics of a product/process/service to identify the level of compliance with normative reference requirements (such as the usability level).

Ergonomic product: product that complies with particular requirements; mainly: it must be user-centered, friendly in interaction, self-explicatory, safe, easy, and satisfying while in use.

Ergonomic test report: the ergonomic test report is a document that records the analytical results and the information necessary in order to interpret the results of the performed tests.

Ergonomics: interdisciplinary science that pursues the design of products, workplaces, and services in accordance with user needs, improving safety, health, comfort, wellbeing, and human performance. It is an interdisciplinary science concerning engineering. anatomy, biology, physiology, psychology, biomechanics, sociology, etc.

Monitoring: activity with which **ErgoCert** checks the maintenance of the compliance with ergonomic requirements. It may be exercised, as per the contract with the client, through the documentation, the field audit on the product and the production, on the market through checks and collections, as well as through analyses of the behavior of the certified products and of their manufacturing companies.

Normative standard: the term is used in the broadest sense, to include other documents such as specifications, technical rules, regulations, etc., issued by standardization bodies, governmental authorities, private associations, consortia or single bodies.

Product: result of the work of all the production units of the company, which must comply with predetermined standards/specifications, be they national or international. The term product is used in the broadest sense, and includes processes and services.

Product ergonomic certification: act with which the certifying body states that, with reasonable reliability, a given product, process or service complies with the requirements in the related Detailed Technical Specifications. The obtained certification level is related to the number of ergonomic tests that have been passed.

Product homogeneous family: a set of representative products defined in a sampling. The main purpose is to identify the homogeneous family in order to group products that may be different from each other, but functionally and ergonomically similar as far as the interaction with the reference users is concerned.

Product requirement: requirement directly related to a product, specified in standards or other normative documents.

Review team: the review team is composed of at least one lead auditor, taking into account the skills and the absence of potential conflicts of role and interest for the auditors belonging to the team. The organization may request – for justified reasons – the team's partial or total change, motivating the reasons in writing. The review team may also be composed of assessors who are not employed by the certifying body, but for whose actions the certifying body is accountable.

Sampling: collection of a sample of the object of the compliance assessment, following a procedure. Selection and collection of a “sample” representative of the product family, following defined methods. Selection of users that are representative of the

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reference utilizers.
Testing area: place where ergonomic activities of analysis, assessment, and check are carried out, physically and materially. It may also be only a specific part of a place.
Type of products: overall hierarchy of homogeneous products to which a specific technical regulation applies.
User-Utilizer: in ergonomics the user is defined in general terms as the person who interacts with the product/service. The terms "user" and "final utilizer" may thus be considered as equivalent. There is also a specification in the level of interaction with the product/service that requires, together with the term "User-Utilizer", the use of the adjective "primary" (user frequently or primarily interacting with the product/service), "secondary" (user occasionally interacting with the product), or further levels in accordance with the product to be tested and the different methods of interaction.

5. LIABILITIES

The liabilities related to the certification are distributed in accordance with the resources effectively involved in the certification activities.

5.1 NON-DISCRIMINATORY CONDITIONS

The access to the compliance assessment is not denied to the stakeholders of said assessment. The compliance assessment and the certification process do not depend on the client's size or on their belonging to any legally constituted association or group whatsoever, or on undue economic-financial conditions or otherwise.

ErgoCert limits its requirements, its assessment, its review, its decision, its monitoring (whether requested) to the ergonomically relevant features related to the scope of the certification.

5.2 UPDATING

The management of **ErgoCert** is tasked with the updating of this Regulation.

6. PUBLICLY AVAILABLE INFORMATION

This Regulation is described on the www.ergocert.org website.

In any case, the clients intending to start the paperwork for the certification with **ErgoCert** may request a hard copy or a protected PDF file.

With the start of the certification paperwork, the client is sent the related technical regulations and/or the technical specifications defined by **ErgoCert**.

7. CONTRACTUAL PROCEDURE

Generally, the ErgoCert sales manager directly communicates with the client about all the information regarding the activity. Furthermore, the information about the certification of the product ergonomic features, at all levels, and about the "Human Centred Design" HCD design processes of the product may be found on the company website.

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7.1 FILLING IN THE CERTIFICATION APPLICATION

To access the services of product certification and/or HCD ergonomic design certification, the prospective client is invited to fill in the form for the certification application (M001-CEP) that, upon request, will be sent or downloaded from the website.

The certification application includes the information necessary to start the contractual procedure:

- Personal details of the prospective client: company name, full name, address, and legal status;
- A description of the products to assess and/or certify;
- The management system and the applicable standards for each, whether they are known to the applicant;
- The undersigning of the release for the data processing pursuant to the privacy policy.

7.2 OFFER PREPARATION

When the application is received, generally within three working days, the ErgoCert sales manager carries out a review to ensure that:

A. the information received with the application is sufficient to submit a proper offer;
B. the requirements for the certification application are clearly stated;
X. there are the abilities to perform the certification activity in relation to the required scope, to the location of the applicant's operating units, and to every particular requirement expressed by the applicant.

If the review shows lack of information, the ErgoCert sales manager gets in touch with the prospective client about all the further additions, for the purposes of the clarity and completeness of communication. When the offer review has a positive result, the sales manager fills in the related part in the certification application, then draws up and sends the offer (M000-CEP) within five working days.

7.3 OFFER ACCEPTANCE AND RELATED PROVISIONS

The client's acceptance takes place with the filling in and undersigning of the offer, or with the sending of the order confirmation. In particular, accepting the offer, the client accepts the contractual conditions and undertakes to:

always operate in compliance with the provisions of the certification regulation;

supply all the necessary information and facilitations for the carrying out of the assessment activities, including the examination of the documents and the access to all to-be-assessed and assessed areas, to the recordings (including the reports from internal audits), and to the staff involved in the resolution of complaints;

make statements about the certification only as far as the purpose and scope for which the certification is issued are concerned;

adopt behavior compliant with the certification regulation and other possible provisions by ErgoCert in relation to the product certification in mass media and/or commercials.

7.4 ORDER CONFIRMATION AND CONTRACT REVIEW

The reception of the client's order confirmation is necessary for the sales manager to review the contract in order to guarantee:

that the certification requirements are clearly defined, documented, and understood;

the resolution of every possible difference in interpretation between the applicant and ErgoCert;

the ability to carry out the certification activity in relation to the required scope, to the location of the applicant's operating

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units, and to every particular requirement expressed by the applicant.

With a positive result, the sales manager records the order in the company's information system (actually opening the order), and carries on with the subsequent activities of planning and service supply.

Whether the review shows any discrepancy with regards to what was initially proposed and/or agreed upon, the sales manager, after getting in touch with the client and assessing and approving any possible modifications, sends an order confirmation to formalize both the conditions and the service activation, perfecting the contractual relationship between the parties. Furthermore, whether during the document assessment or the certification stage there should appear some incongruities in relation to what was stated in the information questionnaire, the offer may be subject to revision by ErgoCert. This exception aside, the terms proposed and accepted together with the offer are generally no longer modifiable.

The contract signed by the client with ErgoCert generally has a predetermined duration, which includes the checking activities for the certification and, whether requested, a given number of monitoring/renewal checks, in compliance with the required certification scheme.

7.5 SERVICE ACTIVATION

The job is handed to the staff tasked with carrying out the activities in accordance with the methods defined by ErgoCert's system procedures. Some indispensable requirements for every resource involved in the process are:

- Qualification of the resource for the required activities;
- Absence of any conflict of interest and guarantee of impartial assessments.

In particular, no resource may be appointed if they have been directly involved, or if they have been employed by a body involved in the design, supply, setup or servicing of the products to certify in a way and for a period that may affect impartiality.

To start the procedure, **ErgoCert** appoints the review team and notifies the client in advance, considering the skills and the absence of potential conflicts of role and of interest for the auditors belonging to the team. The organization may request – for justified reasons - the team's partial or total change, motivating the reasons in writing. The review team may also be composed of auditors/assessors who are not employed by the certifying body, but for whose actions the certifying body is accountable.

The client has the possibility to raise objections, properly motivated and presented in writing, about the composition of the review team or about a single employee. The client may exercise the right of recusal of the assessor (or request a change) within 3 working days from the reception of the communication, due to a conflict of interests or deontologically incorrect behavior.

8. PERFORMANCE OF ACTIVITIES

8.1. PLANNING OF ACTIVITIES

Depending on the required type of certification, and thus on the applicable standards, it is possible to set up different types of audits, checks, assessments, and tests-analyses. The activity sequence is shown in detail in paragraph 7.1 of DTG000. The general flow is as follows:

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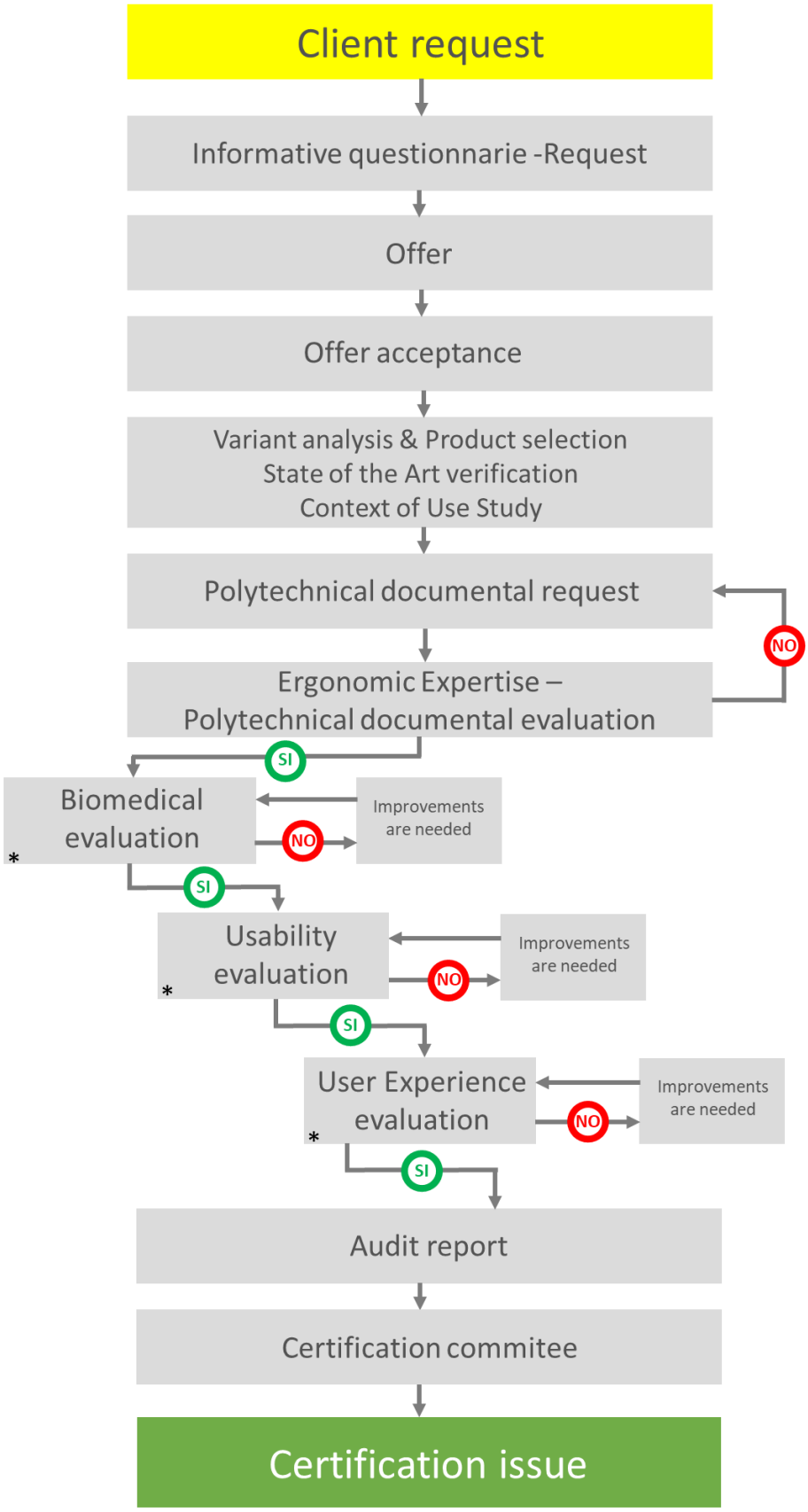

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8.2 TYPES OF AUDIT

8.2.1 PRE-AUDIT (WHETHER REQUESTED)

The pre-audit, whether requested by the client, aims at checking the compliance of a product in reference to voluntary standards, similar products on the market, industry best practices, laws, technical specifications, internal goals, clients' requests.

The pre-audit must highlight:

- the deviations from the norms
- the overcoming of critical issues and instability
- the methods to access certification.

It should be noted that the pre-audit may be carried out only once and cannot last longer than a product certification audit.

8.2.2 FIELD AUDIT AT THE ORGANIZATION

It has the purpose of checking the implementation of what is contained in the technical documents about the product/process/service to certify (applicable standards), and of the necessary certification requirements.

In the case of a process or service, the check is carried out in the places where the services are supplied or the processes are performed, with the aim of assessing the correspondence of the features of the supplied services/processes with the statements in the reference documents for certification (applicable standards).

8.2.3 FIELD AUDIT

As far as the field audit is concerned in relation with the product sector, the client is required to supply one - or more - representative sample of **product homogeneous families** that will undergo the assessments, analyses, and checks required by the applicable standards. ErgoCert is tasked with the acceptance of the sample from a homogeneous family, and will assess its consistency and congruity.

Such samples will have to be accompanied by all the accessories, options, and documents generally supplied to the final user, as well as – when requested – by the attached and/or promotional material used to advertise the product. The products will have to be delivered in their original packaging (whether possible), and accompanied by the set of documents required by the applicable standards, in some cases referred to as "Technical file". and/or by the “Product information sheet for the consumer”.

Further details about the abovementioned aspects will be provided to the client at the time of offer, or at the time of planning.

The supplied samples, adequately prepared, processed, and conditioned (whether applicable), will then undergo the assessments, analyses, and checks required by the applicable standards.

Such activities may sometimes be destructive; in this case the client will be notified in advance of such possibility. Possible polytechnical tests, not carried out by ErgoCert and for which ErgoCert requires technical documentation, will have to be carried out in test labs accredited by Accredia.

Under no circumstances will ErgoCert be liable for the damaging of the samples that undergo assessments and checks, except in the cases, properly documented, of intent by the involved staff.

At the end of the tests the tested products may be:

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1. Kept in the ErgoCert warehouse (whether necessary, for example in the case of comparison samples);
2. Disposed of by ErgoCert in a waste dump (or other method), at the client's expense;
3. Donated to bodies or associations (preferably with the client's written release);
4. Given back to the client. This latter method requires such products to be kept no longer than 20 working days since the end of the tests (with e-mail notification to the client) in the ErgoCert warehouse. After that time, the storage or the disposal will be charged (the cost of such operation will have to be notified in advance to the client and billed separately).

During all the stages of assessment and checking, the client or a representative is allowed, following an explicit request, to take active part in the performance of said stages, supporting the technical staff.

Such a circumstance may apply only in the cases in which the assessed product/products belong to the same company and for technical reasons, and in any case at the sole discretion of ErgoCert. The presence of competitors' products may be a condition for the cancellation of such possibility, again, at the sole discretion of ErgoCert. In cases of non-compliance that may affect the performing of subsequent tests, the client will be promptly notified and, after analyzing the non-compliance and the solution suggested by the client, we will proceed, in agreement with the client, with the assessment of the possible impacts on the modified product. On the basis of the assessment results, we will proceed with:

- the repetition of the test or tests that caused non-compliance;
- the repetition of other possible tests that, at the sole discretion of ErgoCert, may be affected by the modifications introduced to remedy the non-compliance. Such possibility will lead to the issue of a specific cost estimate that will be notified to the client;
- the suspension or definitive termination of the certification activities. Following the tests, a test report compliant with the requirements of the applicable standards and the ISO/IEC 17025 standard will be issued.

As far as the field audit is concerned in relation with the process-service sector, the client allows the checking and performing of ergonomic assessments with or without equipment.

8.2.4 PRODUCT, LINE, FACTORY OR PRODUCTION PLANT INSPECTION

The inspections to products (products, processes, services), to lines, to factories or to production plants, for the purposes of the voluntary ergonomic certification, will be carried out as indicated in the previous chapter, “Field audit,” except that only the ergonomically relevant activities related to the product, process, service subject of certification will be considered. Such activities may be carried out even before the certification stages, in order to set the normative status and the references to technical specifications. The client may also decide not to proceed with the certification activity.

8.3 ASSESSMENT AND RESULTS

Once the assessment activities have been completed, if some non-compliance (NC) has come up, it may be recorded by the person in charge of the assessment team in the audit report. NCs are defined as “major” or “minor”.

Non-compliances are *“major”* (MNC) when they deal with the lack of compliance with one or more specific requirements of the standards and/or technical specifications. MNCs, accepted by the applicant (who always reserves the right), prevent the continuation of the certification procedure until their resolution, which will imply a further audit.

Non-compliances are *“minor”* (mNC) when they have a sizeable impact on the coverage of a specific technical requirement. The procedure moves forward with the certification approval (by the appointed Committee). The maintenance of the certification

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depends on the reception and acceptance by ErgoCert within 90 days (or any agreed upon time) of the formal proposal of handling of the findings (causes, remedial actions, and related times). In lack of a formal proposal of handling within the required time, the certificate will be suspended.

The handling of the findings may include further tests set up by the assessment team at the applicant's expense. Furthermore, it is up to the assessment team to agree with the applicant upon a verification plan for the subsequent monitoring, detailing in particular the tests to be performed periodically.

Observations (OSS). Observation consists in the audit team reporting to the organization about improvable aspects (for example about the documentation), beside its compliance and effectiveness.

8.4 CERTIFICATION LEVELS

ERGONOMIC CERTIFICATION – 1 STAR

The ergonomic certification "1 star" proceeds along the following steps:

- Document checking in the polytechnical/normative area (attestation compliance and/or results of tests supplied by the manufacturing company)
- Analysis of the possible variants (for example, configurations, families) and selection of products to test as representative of the whole family (in order to select a representative sub-group to test analytically, and then extend the certification to the family)
- Document benchmarking on competitor products (check of the state of the art of the competitors/of the market)
- Study of the context of use (study of users, tasks, application environment)
- Ergonomic expertise (on the prototype and/or finished product): compliance with the general ergonomic principles (with possible technical checks with or without users, depending on the case). The outcome is described in the audit report (with the possible identification of critical issues, deviations, and non-compliances). With a positive outcome, the product is certified with 1 star (or, upon request, it accesses the subsequent stages)
- Dispatch to the committee for the certification
- Examination by the committee, with a possible request for integration. Issue of the ergonomic certification – 1 star

COMPLIANCE WITH ERGONOMIC PRINCIPLES

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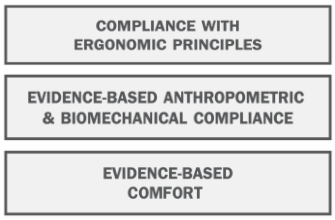
ERGONOMIC CERTIFICATION – 2 STARS – BIOMEDICAL AREA (ANTHROPOMETRICS AND/OR BIOMECHANICS)

The ergonomic certification "2 stars" proceeds along the following steps:

- Application of the standards to the client's product (drafting of the technical specification, whether not available)
- Audit in the biomedical area: technical-instrumental tests with users and check of compliance with the technical specification. The outcome is described in the audit report (with the possible identification of critical issues, deviations, and non-compliances). If the outcome is negative the product is not certifiable. If it is positive, the product is certifiable with 2 stars (or, upon request, it accesses the subsequent stages)
- Dispatch to the committee for the certification
- Examination by the committee, with a possible request for integration. Issue of the ergonomic certification – 2 stars

Note: along with the label "*compliance with ergonomic principles*" comes the label "*evidence-based anthropometric …*" or the label "*evidence-based comfort*" depending on the type of tests undergone by the product.

(for example, a seat may be certified in relation to comfort, while a professional washing machine may be certified on the basis of its compliance with anthropometric and biomechanical principles)

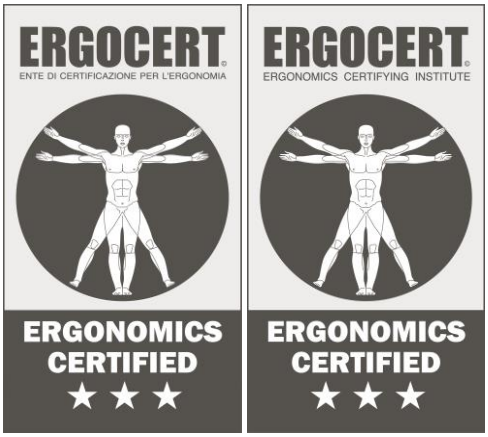


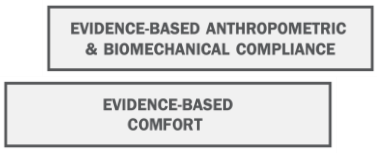
ERGONOMIC CERTIFICATION – 3 STARS – PSYCHOSOCIAL AREA (USABILITY)

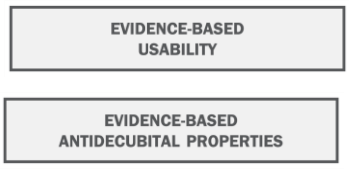
The ergonomic certification "3 stars" proceeds along the following steps:

- Application of the standards to the client's product (drafting of the technical specification, whether not available)
- Audit in the psychosocial area (usability): usability tests with users and check of compliance with the technical specification. The outcome is described in the audit report (with the possible identification of critical issues, deviations, and non-compliances). If the outcome is negative the product is not certifiable. If it is positive the product is certifiable with 3 stars (or, upon request, it accesses the subsequent stages)
- Dispatch to the committee for the certification
- Examination by the committee, with a possible request for integration. Issue of the ergonomic certification – 3 stars

Applicable labels







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ERGONOMIC CERTIFICATION - 4 STARS – PSYCHOSOCIAL AREA (USER EXPERIENCE)

The ergonomic certification "4 stars" proceeds along the following steps:

- Application of the standards to the client's product (drafting of the technical specification, whether not available)
- Audit in the user experience area (ux): tests with users and check of compliance with the technical specification. The outcome is described in the audit report (with the possible identification of critical issues, deviations, and non-compliances). If the outcome is negative the product is not certifiable. If it is positive, the product is certifiable with 4 stars (or, upon request, it accesses the subsequent stages)
- Dispatch to the committee for the certification
- Examination by the committee, with a possible request for integration. Issue of the ergonomic certification – 4 stars

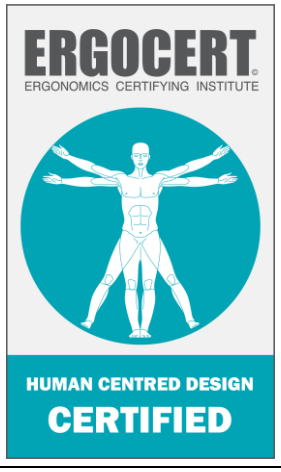
Applicable labels

COMPLIANCE WITH ERGONOMIC PRINCIPLES	EVIDENCE-BASED ANTHROPOMETRIC & BIOMECHANICAL COMPLIANCE EVIDENCE-BASED COMFORT	EVIDENCE-BASED USABILITY EVIDENCE-BASED ANTIDECUBITAL PROPERTIES	EVIDENCE-BASED USER EXPERIENCE

PRODUCT DESIGN - HUMAN-CENTRED DESIGN CERTIFICATION PROCESS (HCD)

The ergonomic certification of the human-centred design (HCD) proceeds along the following steps:

- Application of the standards related to the human-centred design (HCD)
- Audit for the check of compliance with the technical specification in reference to the outputs of the HCD stages of the product design process. The outcome is described in the audit report (with the possible identification of critical issues, deviations, and non-compliances). If the outcome is negative the product is not certifiable. If it is positive, the product is HCD certifiable or, upon request, a certification level for the product (stars) may be added.
- Dispatch to the committee for the certification
- Examination by the committee, with a possible request for integration. Issue of the HCD ergonomic certification.



HUMAN CENTRED DESIGN CERTIFICATION

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INTEGRATION BETWEEN PRODUCT CERTIFICATION AND HUMAN CENTRED DESIGN PROCESS

The obtainment of the "Human Centred Design" product design certification allows the addition of one star to the product ergonomic certification already obtained.

9. CERTIFICATE ISSUE

The ErgoCert certificate is the document with which **ErgoCert** certifies that the company designs and produces products/processes/services complying with the ergonomically relevant applicable standards, contained in the **ErgoCert** General Technical Regulation (Disciplinare Tecnico Generale - DTG), in the Technical Regulations (Disciplinari Tecnici - DTA), and in the Technical Specifications (Specifiche Tecniche - ST), as reference for the certified product, for which the company guarantees the identical replicability in the mass production of the tested sample/samples.

The procedure described in this paragraph is applied in all the checks carried out by **ErgoCert** for the purpose of certifying the product ergonomic features, be they preparatory for the certification, about monitoring, or about renewal.

The Certification Committee is tasked with deciding about the possibility to issue, suspend, or cancel the certificate subject to checking through the examination of the check report and of the other documents and data making up the certification paperwork.

During the examination of the certification paperwork, the Certification Committee may deem necessary to ask the assessment team for clarification, or even for further research, with a new activity among those mentioned in the previous paragraph.

Every assessment by the Certification Committee differing from the assessment team's is promptly notified to the client.

The members of the Certification Committee, although in possession of the technical skills, may not in any way take part in the checking activities, or in the possible preliminary audit. When the Certification Committee gives a favorable opinion, **ErgoCert** issues a certificate of compliance, which is forwarded to the client. The certificate validity is defined from time to time by the relevant reference standards.

The certificate issue automatically implies the permission for the client to use said certificate, the possible numerical code that identifies the **ErgoCert** notified body, whether applicable, and the possible **ErgoCert** brand, whether stated in the contract, as set out in the reference standards and in this Regulation, and/or in the Brand Use Regulation with which the client will be provided at the time of obtaining the Certification.

The document attesting the **Certification** is made up of a **certificate** that mentions:

- an identification number, with the corresponding revision if the certificate has been reissued;
- the client's company name, with the contact information for the certification (legal address, production sites),
- the applied reference standards,
- the scope, with reference to possible exclusions,
- the category of the product subject to certification,
- the first issue date for certification,
- the expiry date (where applicable),
- the logo of the accreditation body,
- the time limit for periodical monitoring or renewal,
- the signature of the **ErgoCert** manager or of a person appointed by him and legally authorized to sign.

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The issued certification has a three-year validity, and is subject to the checking and monitoring prescribed in the related regulation/technical specification. The certification validity is subject to the compliance with the technical and economic conditions described in this Regulation.

Whether the Deliberative Committee decides not to issue the certification, a new certification application may not be put in before a period of three months.

10. CHECKING (EVEN WITHOUT PRIOR NOTICE)

Checking without prior notice has the purpose to verify that the client, holder of the certificate, maintains an effective system to ensure the compliance of the certified products with the requirements of the applicable standards, and may also be requested by Accredia.

Checking begins with a review of the client's documents, in particular those documents that, as compared to the previous checking, have been newly issued, or have been updated or reviewed. Special attention is given to checking the remedial actions (and their effectiveness) in relation to the previous findings, duly notified to the client.

In the event of a negative assessment about the effectiveness of a remedial action undertaken for a non-compliance or observation identified during a previous inspection, as well as in the event of recurrence of an observation about the same requirement, the inspection team assesses the results of the finding.

Further checking involves the correct use of the **ErgoCert** certificate, as well as the correct handling of the possible complaints and reports from the customers and interested parties.

The outcomes of the checks without prior notice undergo the assessment of the Certification Committee, in order to confirm or deny the validity of the certification.

Following the deliberation by the Certification Committee, **ErgoCert** notifies the client about the decision and enforces the provisions: confirmation, suspension, or withdrawal of the certificate.

The client is promptly notified about the decisions taken (to that end, see also paragraph 14).

In the event of an improper use of the means of communication on the part of the company or another party (for example, press, websites, etc.) the Certification Committee will assess on a case-by-case basis the actions to undertake according to this Regulation.

11. REGISTER OF CERTIFIED CLIENTS

ErgoCert updates its register of certified clients with every new issue, or upon the renewal of the certificate, and, whether required by the applicable standards for every product certification scheme, notifies the competent authorities according to the established schedule.

The information made public (unless otherwise specified by the reference standards) includes:

- Certificate code;
- Client's company name;
- Types of certified products, including a clear identification of the certified product;
- Validity of the certification.

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For any information about certificates issued by **ErgoCert** the client may refer to the area reserved for clients in the ErgoCert website www.ergocert.org or directly contact the office, using the details in the contact section or reserved area in the website www.ergocert.org.

12. MODIFICATION OF THE CERTIFICATION REQUIREMENTS

ErgoCert is committed to providing its clients and interested parties with all the necessary information related to the modifications to be made to the requirements for the certification. In making said modifications, **ErgoCert** will take into account the opinions expressed by the interested parties before deciding on a precise form and date for the modifications. Following the decision and the publication of the modified requirements, **ErgoCert** will check that every client implements all the necessary adaptations within a reasonable established period. **ErgoCert** will decide according to this Regulation about the issue, reissue, or cancellation of previously conferred certificates. **ErgoCert** will in any case have to verify the compliance of the requirements with this Regulation in order to make the certification procedure homogeneous and compliant for previously conferred certificates.

In the event of a modification of the certification requirements, the clients are allowed to withdraw without penalty from the certification.

13. REFERENCE CONDITIONS FOR THE CERTIFICATION AND USE OF THE BRAND

After obtaining the certification, the client must establish and implement a procedure related to the handling of said certification (and in particular to the use of the certificate and the **ErgoCert** brand) in every means of communication.

The procedure must indicate the function or functions of the client who is responsible for said handling, and in particular for the ways of using the certificate and the brand, in order to ensure the compliance with the following requirements.

As far as the **ErgoCert** registered trademarks presented in the table attached to this document are concerned, the following rules also apply:

- the issued certification mark may be used solely in advertisements (brochures, website, commercial videos about the product, multimedia tools, etc.);
- the right to use the issued certification mark (in its integrity, that is, without making any graphic modification, and following the correct wording, colors, etc.) applies solely to the products checked at the production site mentioned on the certificate itself. In the event of outsourcing production, the possibility of checking at the site will be taken into account.
- the issued certification mark may be used for advertising purposes only in reference to the activities allowed by the contract signed with **ErgoCert**.

After obtaining the certification, and for all its period of validity, the client may mention it in their technical and commercial materials, in the terms defined by the various standards, provided that every mention is made correctly, in such a way as not to mislead the final user and the product stakeholders; in particular, it must be clear that the certificate is solely about the certified "product", which means that particular product, that particular appliance, component or system expressly mentioned on the certificate itself, and not others, not even the organization's management system (for example, the quality system or other type of system).

The correct use of the certificate and, in general, the correctness of the references to the certification are taken into account during the monitoring and renewal checking. If the review team detected some non-compliances in such area, or an incorrect use of the

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certificate, there would be the conditions to suspend or withdraw said certificate, depending on the degree of severity.

In the event of suspension or withdrawal of the certificate, the client will be committed to refraining from using it and any other mention of the certification (**ErgoCert** brand) in every means (catalogues, videos, advertisements, various communications, etc.) within 2 months at the most.

Whether this should not occur, **ErgoCert** reserves the right to take legal action.

Partial copies of the certificate are not allowed; it is possible to enlarge or downsize it, provided that its structure is not distorted, and the certificate is uniform and readable in any case.

It should be noted that both the ERGOCERT brand and the ACCREDIA Accreditation body brand, reported on the certificates issued by **ErgoCert**, may not in any way be used by the client organization (for example, affixation on headed paper, brochures, etc.) differently from what is stated in the Brand Use Regulation.

14. CERTIFICATE SUSPENSION AND WITHDRAWAL

For serious reasons, and at its sole discretion, **ErgoCert** (namely, the Certification Committee) is entitled to suspend the validity of the issued certificate for a given period.

In such cases, for the period considered, the client loses the right to mention said certification.

The certificate suspension/withdrawal may occur, whether applicable, as well as in the cases defined by the reference standards, also when the client:

- mentions the certification or uses the ErgoCert brand differently from what is described in this Regulation;
- does not keep a register for the complaints and the reports coming from the interested parties regarding the activities falling under the certification, and of the related corrective actions;
- is not up to date with payments for the activities that have already been carried out;
- does not comply with the conditions set by **ErgoCert** to cancel the certificate suspension, including the handling of minor non-compliances and observations;
- significantly modifies its production / management methods for the certified product without notifying **ErgoCert**;
- stops the production or the supply of the certified products for more than one year;
- does not promptly notify **ErgoCert** about any action from the public authority and/or pending legal proceedings, accidents or serious injury regarding the certified product.
- goes out of business.

The maximum period of suspension is 6 months since the certificate expiry.

Whether there is a pendant judicial proceeding or the organization has been notified of the commencement of a judicial proceeding, **ErgoCert** reserves the right to carry out a precautionary suspension of the certificate, notifying the competent bodies (Ministries, ACCREDIA Accreditation body).

The suspension may be cancelled when the elements substantiating the opening of the proceeding have been clarified, and there is no objective evidence of the involvement of the certified product/service, or of its elements or liabilities, in said judicial proceeding according to the following sequence:

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- the certification contract is terminated;
- they notify that they do not intend to carry on with monitoring checks;
- non-compliances come up during the monitoring checks or checking without prior notice;
- they formally request **ErgoCert**;
- when **ErgoCert** modifies the rules of the certification system, and the client cannot or does not want to comply with the new requirements.

In the event of certificate suspension or withdrawal, **ErgoCert** notifies the client in writing, also providing the conditions the client must fulfil, and the time period to do so, in order for the suspension to be canceled or the certificate to be reissued.

In the event of certificates issued in the context of "mandatory" certification, **ErgoCert** notifies the competent authorities about the certificate suspension/withdrawal.

In the event of suspension or withdrawal the client may not mention the certification again in any way. The violation of this clause may imply the use of legal action by **ErgoCert**.

Moreover, the client whose certificate has been suspended or withdrawn must immediately notify their own customers. It should also be noted that, in the event of certificate suspension notified for serious anomalies of the product subject to certification, the client will have to stop immediately the dispatch of said product ready to be sent and/or in stock, and carry out the necessary actions to block the in-stock products and/or to recall the products from the market.

The conditions for the cancellation of the suspension or the reissue of the certificate are defined by **ErgoCert** depending on the motivations that have brought about the decision to suspend/withdraw, and in compliance with the requirements of the applicable standards.

15. HANDLING OF CUSTOMERS' AND INTERESTED PARTIES' COMPLAINTS AND REPORTS

The **ErgoCert** client must set up and carry out a documented procedure to handle complaints and records, in order to ensure:

- the recording of the eminently "ergonomic" complaints and of the reports received by their customers and interested parties regarding the activities, the production and supply of the products to which the certification applies, and which may impact the compliance with the certification requirements;
- The performing of adequate inquiries about such complaints and reports, and the related recording;
- The adoption, whether necessary, of corrective actions and their recording. The paperwork and the register must be put at the ErgoCert team's disposal during the various checks. Moreover, said documents must be accessible also to the ACCREDIA representatives.

16. MODIFICATIONS TO CERTIFIED PRODUCTS

The client intending to make any modifications to the certified product that may affect the ergonomic compliance, safety, and legality of the certified productions, including the modification of lines, processes, and production sites, must promptly notify **ErgoCert** in writing. It should be noted that, for the purposes of the certification, a product differing from the certified one is to all intents a "new product" and, as such, requires a new check before being declared as compliant.

ErgoCert assesses the effective need to carry out, on the basis of such modifications, supplementary checks, possibly

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complemented by a certificate review, or to start a new certification procedure, taking also into account the type of existing certificate. The non-compliance with this provision may imply the certification suspension. The client is also required to promptly notify **ErgoCert** in the case of exceptional events, judicial proceedings, accidents, emergencies, non-compliances with the law.

The information must be related to the occurred event, and complemented by a report describing the handling of the event and the repercussions it has had on the management system.

ErgoCert examines the information and the report in order to assess its completeness and thus decide which action to undertake:

- certification confirmation;
- need to carry out a supplementary audit;
- certification suspension or withdrawal.

A similar procedure applies in the event of variation of the company name or other modification requested by it.

17. CERTIFICATE VALIDITY

The issued certificates are valid for a period established by the reference standards, generally three years.

During the period of validity of the certification, ErgoCert will carry out, using qualified staff, monitoring activities through documental and/or technical audit. The monitoring activity has the purpose of checking the maintenance of compliance with the requirements of the certified ergonomic features described in the reference technical document.

The certificate expiry date is indicated on the certificate itself. At the time of the natural expiration, the client has the right to choose whether to maintain the certification active or terminate it. On the basis of the client's decision the following conditions may occur:

- Certification termination: the client who does not intend to carry on with the certification activities is obliged to eliminate every mention of the certification from the products, from the material related to the products (for example, packaging), or from the documents (advertisements and/or technical communications, etc.).
  The client may place on the market products that have been manufactured within the expiry date of the certificate validity, within a period of 6 months since said expiry date.
  The products that are not in stock on the expiry date of the certificate validity may no longer mention the reference to the certification and, in the event of mandatory certification, may no longer be placed on the market in association with the **ErgoCert** certification. In such cases, **ErgoCert** reserves the right to carry out an inspection at the client's warehouse to check the actual stock on the expiry date of the certificate validity.
- Certification renewal: in order to renew the certificate validity, it is necessary to carry out a new check before the certificate expires. The extent of this activity depends on the type of issued certification. **ErgoCert** reserves the right to assess on a case-by-case basis the extent of the check to carry out, also on the basis of the product complexity, of the manufacturing process, or of the potential risks posed by the product itself to the final user.

18. REQUIREMENTS FOR THE CONVERSION FROM OUT-OF-ACCREDITATION CERTIFICATES AND FOR OUT-OF-ACCREDITATION CERTIFICATION

18.1 CONVERSION FROM OUT-OF-ACCREDITATION CERTIFICATES

A company in possession of an ergonomic product certification issued by **ErgoCert** prior to the ACCREDIA accreditation may

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convert their certificate through a check by **ErgoCert** of the evidences and conditions defined in previously used technical specifications, and the compliance with possible subsequent technical specifications. **ErgoCert** will notify the company about the confirmation of the requirements or the need for supplementary tests and checks, to give the standard and the technical specifications subject to accreditation completeness and compliance.

18.2 OUT-OF-ACCREDITATION CERTIFICATES

To certify out-of-accreditation regulations the same rules as this Regulation apply.

The certificate conversion is guaranteed without further requirements whether **ErgoCert** accredits the regulations issued without accreditation.

19. PARTICULAR REQUIREMENTS FOR CLIENTS ALREADY CERTIFIED BY ANOTHER BODY

A company in possession of a product certification issued by another ergonomic product certifying body may request the certification, for the same product, by **ErgoCert,** provided that the certification by the previous body is no longer valid.

There are no particular restrictions for the certification of products different from those already certified by another body or for certifications other than the product certification.

20. CONFIDENTIALITY OF INFORMATION

ErgoCert assures that all the information collected during the activities related to the certification or in the course of the monitoring checks is handled with the utmost confidentiality, unless otherwise specified by:

1. legal provisions;
2. provisions by the accreditation and/or notification bodies;
3. certification scheme owners. In such exceptional cases, the client is notified about what information is disclosed to third parties.

To that end, the **ErgoCert** staff involved in the certification activities undersign a formal commitment to confidentiality, including the provisions described in the current legislation on the subject of data protection (European Regulation – EU – 679/2016 - GDPR).

Upon request the client is provided with a copy of such document.

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21. COMPLAINTS AND APPEALS

21.1 HANDLING OF COMPLAINTS

For the purposes of this Regulation, by the term “complaint” it is meant a formal protest made in writing when one believes to have suffered injustice or damage. Any client and any interested party may make a claim against **ErgoCert** and its activities.

A complaint may be filed by organizations/clients (or other parties), and may be about the modes of operation used by the **ErgoCert** staff during the various stages of the certification activities;
A complaint may also be about the certification of a company different from the complaining one;
A complaint may, more generally, have the most diverse sources, though always concerning **ErgoCert**'s certification activity.

ErgoCert duly takes this into account under the following conditions:

the complaints must be filed in writing (any medium is accepted), and must describe the subject of the complaint in detail;
the claimant's name and contact details must be reported;
the reasons for the complaint must be reported in detail.

Whether such information is not included in the complaint, the claimant is contacted for the necessary clarifications. Whether the information is not supported by adequate documental or testimonial evidence, **ErgoCert** will decide whether to carry on with the inspection or cancel the procedure. If the unjustified complaint is linked to a competitor company, certified by **ErgoCert**, the latter will decide about the possibility to start an inquiry to check that such complaint is not a discrediting action on the competitor’s part.

The complaints are handled through a specific management system procedure, and for each of them a first reply will be sent within ten working days of receipt.

The complaints are examined by the manager and/or a person appointed by him (for example, the quality manager or the technical manager), who carries out the appropriate investigations and examinations, also interviewing, whether applicable, the technical and operating staff involved.

In any case, the complaint will be assessed by staff members who have not taken part in the activity subject of said complaint. Whether the situation requires it, **ErgoCert** reserves the right to carry out a supplementary checking in order to verify the subject of complaint.

At the end of the complaint handling procedure, **ErgoCert** notifies the claimant in writing, reporting the outcome of the investigations and the possible measures adopted.

The information related to the complaint and its resolution may not be made public without the interested parties' consent.

21.2 HANDLING OF APPEALS

By the term “appeal” it is meant a request for the cancellation or the modification of a provision that is considered detrimental to one's rights or interests in relation to the decisions made by **ErgoCert** during the certification activities.

The client that employs **ErgoCert**'s certification services has the right to file written appeals with reference to the decisions and measures adopted by **ErgoCert** following a certification activity, in order for such decisions to be reviewed.

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Filing an appeal, the claimant will have to mention the organization's details, the subject of said appeal, the detailed underlying motivations, the possible attachments to support said motivations, and the organization's legal representative's signature. It should be noted that the lack of one or more of the aforementioned elements is a reason for the appeal to be rejected. In such cases, **ErgoCert** will notify the claimant with the motivations for the decision.

Conversely, whether the appeal is acceptable, the management will start a review for the appeal, and for the reasons that have brought forward said appeal, involving the interested parties.
The appeal will be examined by a commission made up of staff members who have not taken part in the certification activity subject of said appeal.

At the end of the investigation, within two months of receipt of the appeal, the claimant will be notified about the outcome of the checking.

21.3 LITIGATIONS

Whether a litigation should arise between ErgoCert and one of its clients, or other interested party, the place of jurisdiction is Udine.

22. CERTIFICATION TARIFF

ErgoCert preferably defines, whereas possible (activity standardization), the economic conditions applicable to the certification activities in order to make sufficient profit to guarantee independence in the performance of its activities, and to allow the constant improvement of the offered services.
ErgoCert's tariff includes the following elements (whether applicable):

Submission of the certification application;
Examination of the documents;
Assessment audit, reporting separately those related to:

- initial/supplementary/extraordinary assessment,
- extension, monitoring, renewal, exam session (at the site, the company headquarters, or **ErgoCert**)

Certification issue;

- travel expenses, extra expenses (room and board, car expenses);
- activities attributable to supplementary inspections;
- possible check at the lab (third-party) for the purposes of the qualification;
- annual fee whether applicable.
- possible annual fee for the use of the **ERGOCERT** brand.

Said tariff, and its possible subsequent modifications, will be forwarded by the certifying body to the monitoring authorities, together with the certificates, whether applicable and/or required.
Possible urgent procedures, expressly requested by the client, may imply an increase in costs.

23. BILLING

The billing for the services provided by **ErgoCert** takes place in accordance with the terms established at the time of offer and

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contract stipulation. The following also applies:

- For the on-site or field ergonomic tests, an advance between 30% and 50% (depending on the order amount) is due before the start of the activities mentioned in the contract. In the alternative, **ErgoCert** punctually mentions in the contract specific terms of payment depending on the complexity and/or duration of the job.
- Whether the client cancels in writing, the scheduled activities confirmed in the contract within 20 working days before the agreed upon date, **ErgoCert** reserves the right to charge, for the estimation study expenses, the amount mentioned in the offer and/or order confirmation, together with other possible (documented) costs incurred for the activities mentioned in the contract;
- In the event of unilateral termination of the contract by an already certified client, concurrently with a monitoring check, **ErgoCert** reserves the right to charge the amount for the failure to perform the check whether the written notification about the termination does not arrive at least 4 months in advance.
- In the event of interruption of the certification activities due to any reason whatsoever, the client receives from **ErgoCert** an invoice for all the services performed up to the moment of interruption (in particular whether, after the signing of the contract, the client does not start the certification activities, they receive in any case an invoice for the amount of the starting of the paperwork).

ErgoCert reserves the right to review the contract documents whether, during the certification activities, it encounters any variation from the terms stated by the client, according to which the offer was issued.

24. CLIENT'S AND ERGOCERT'S DUTIES

The client is obliged to:

§ 2: comply with the contents of this Regulation.
§ 6.1: expressly state that they do not have submitted any certification application, for the same device, product or tool, to any other notified body in case of certification for the purposes of the CE mark in compliance with EU directives.
§ 8: accept the possible presence of observers from **ErgoCert** or the ACCREDIA accreditation body during the various stages of performing the certification activities.
§ 10.1 (periodical checks): provide the means and help necessary to carry out the scheduled periodical checks.
§ 13: mention the certificate in the ways and with the means allowed by the rules applicable to said certificate.
§ 16: promptly notify about the intention to modify a certified product;
§ 16: promptly notify in the case of exceptional events, judicial proceedings, accidents, emergencies, non-compliances with the law.
§ 22: keep up to date with the payment of invoices.

ErgoCert's duties:

§ 8: **ErgoCert** is committed to operating in compliance with the requirements set down in the reference standards;
§ 10: (periodical checks): in the event of a negative outcome of the periodical check, **ErgoCert**, notifies the competent authority;
§ 12: **ErgoCert** is committed to providing its clients and interested parties with all the necessary information related to the modifications it intends to make to the certification requirements;
§ 19: **ErgoCert** assures that all the information acquired during the certification activities or the monitoring checks is handled with the utmost confidentiality.