CHANGE LOG

Version	Issuance date	Description of changes to previous version
03	30/01/2020	- Association of an identification code to the document - Insertion of section "Change log" and the approvals table - General review of the content of the document: change of its structure, with insertion of new paragraph and deletion of some others, insertion of new information on the process described and amendments to others - Replacement of Technical management department and the General Management with Service Management in complaints management - New section added, on declaration of documentation review of non sterile class I Medical Devices.

APPROVALS TABLE

Name and surname	Business Function	Role	Date and signature
Silvia Manetto	Quality Assurance	Author	30/01/2020
MariaFrancesca Spinosa	Assicurazione Qualità	Reviewer	30/01/2020
Luca Bedonni	Service Management	Approver	30/01/2020

1. OGGETTO

This Regulation deals with the ECM Voluntary *Mark* for Product Certification, hereinafter referred to as "Mark", and provides information and instructions on:

- meaning of such a *Mark*
- terms and conditions for products manufacturers to ask ECM the release of the *Mark*
- the process of ECM to release such a *Mark*
- how to use such a *Mark*.

The use of Voluntary *Mark* (and the related certificate of compliance, see below) is closely linked to the terms reported in this Regulation. Please do not use the *Mark* before having read carefully this Regulation.

This Regulation deals with the activity described in paragraph 18, as well. This activity aims at checking compatibility of the documents of Medical Devices Manufacturers with the European standard specific for such a kind of products (93/42/CEE Directive, Annex VI.

2. SCOPE

With regards to organizations, the voluntary *Mark* can be released by ECM to all kind of organizations, either established in the European Economic Area, or non-EU, without any discrimination.

The products object of the Mark and the standards to apply for the conformity assessment must take into account the following constraints:

- the *Mark* may be issued only for products manufactured in series;
- the use of specific references different from the standard ones should be restricted when a proper national or international standard is not available; these specific references should be the ones defined by the standardization bodies as final draft even though not approved yet.

3. DISTRIBUTION OF THIS REGULATION

This Regulation is available to whom is concerned, on the webpage:
www.entecerma.it
It is ECM's responsibility to make available on the webpage the updated version of this Regulation.

4. DEFINITIONS

MARK: it is the official expression of the results of the evaluation of the documentation (technical file) related to a product, aimed to demonstrate product compliance to the requirements of specifically identified standards/regulations.
HOLDER OF THE MARK**:** organization that applied for and obtained the Mark release by ECM
COMPLAINT: form of unsatisfaction, both verbal and written on services provided by ECM;
CLAIM: formal appeal, on behalf of the subject, having specific causes, against decisions taken or evaluation expressed by ECM.

5. WHAT ECM VOLUNTARY MARK IS

ECM can perform inspections of the Technical Documentation of manufacturers or their suppliers

This documentation review is aimed to verify the compliance of many aspects, among the others:

- whether the standards used are harmonized with the reference Directive
- whether the report contains evidence of compliance to the harmonized standards
- whether the declaration of conformity mentions properly harmonized standards
- whether there is a user manual
- whether the product label reports the CE mark
- whether there is a model of the declaration of conformity

These inspections are voluntary and they are not carried out by ECM as a Notified Body; as an independent party though. Furthermore, such an activity is not consultancy.
For these reasons, the output of this documentation review is a traceable and reliable **opinion** of ECM as independent party, that is reported by ECM itself in writing inside a document called "voluntary certificate of compliance", issued by ECM as well.

6. AIM OF VOLUNTARY MARK/CERTIFICATE

Purpose of the *Mark* it is to give evidence (with the level of confidence associated to a review carried out by an independent party) that the product meets the standard(s) or technical specifications. This purpose is achieved by means of an evaluation of the technical documentation, carried out prior to the release of the *Mark*.
The voluntary certificate can be used only in the following cases:

- to show the customer of the manufacturer that the latter carried out all the necessary technical tests and that there is a technical file concerning the CE marking, but without showing the documentation (for instance any copy of test reports) to the customer - except when required by law
- to provide the manufacturer Management with the results of an inspection of its own documentation, to assess its compliance to requirements of the Directives
- when the customer does not have enough skills to perform the evaluation of the tecnical file of its supplier
- to allow the customer to have the evidence that the product documentation of the supplier was verified by an independent third party on a voluntary basis.

7. TERMS TO USE THE *MARK*/CERTIFICATE

The voluntary *Mark*/certificate:

- can only be used to prove that a product was actually tested **between organizations that recognize this Regulation**
- does not have any legal value, unless it is used between private companies with specific agreements between them
- is NOT required by law (it is voluntary) and it is intended for use between private companies
- **can only be used for commercial, advertising and promotional purposes and can not claim at all the product compliance to national or international laws, directives and regulations. In particular, any promotional literature, including what is published on the Internet, must clearly report the voluntary nature of the *Mark*.** The documents released by ECM cannot be reproduced, totally or partially, in such a way that could cause the consumer to deem the final product compliant to any applicable

mandatory legislation. The documents released by ECM may be mentioned only with the very same wording and in full form and including the date of issuance
- **is NOT an authorization by ECM to apply the CE mark to a product**
- does not originate from customs needs nor to demonstrate to Authorities compliance of products to requirements for CE marking
- is NOT a legal requirement to apply the CE marking on the product
- **can NOT be used to demonstrate product compliance to Authorities**
- **can NOT be used during Governments' ispections**
- can be used only with purposes authorized by law.

Please, note that some Directives require the use of Notified Bodies: **the voluntary certificate is NOT associated with any activities of the Notified Bodies nor is mandatory to fulfill any law requirements. On the contrary, it states the opinion of ECM that the manufacturer, under its responsibilty, can apply the CE mark on the product if it is compliant to the applicable directives**.

The voluntary certificates are NOT issued by ECM as a Notified Body or accredited laboratory.

The certificate issued by ECM as Notified Body is a ssociated to a purpose completely different from the one of the voluntary certificate: the voluntary certificate has nothing to do with the certificates issued by ECM as a Notified Body. Do not mismatch these two types of certificates: if any doubt arise, please get in touch with ECM.

The holder of the *Mark* can NOT use the voluntary certificate for any purpose **out of** the ones listed above without the official authorization of ECM prior to do so.

If any doubt related to the use of the voluntary *Mark* and certificate arise, do not use them and, please, get in touch with ECM:

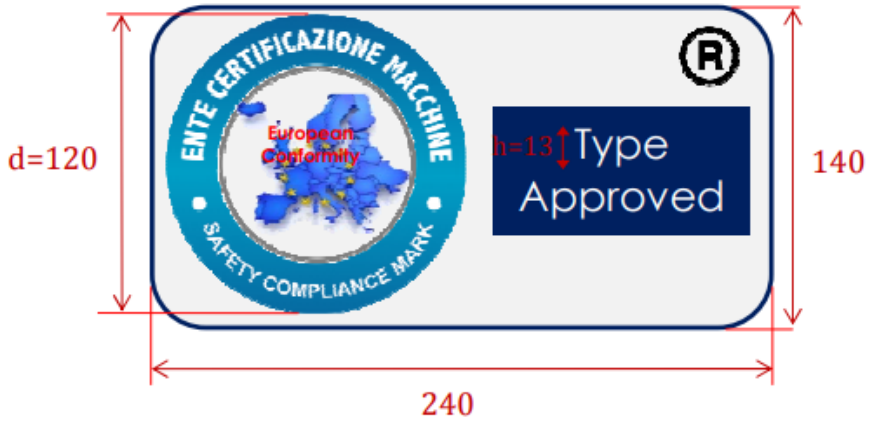
info@entecerma.it

8. CHARACTERISTICS AND DESIGN OF THE *MARK*

The mark's shape is a rectangle with rounded edges, with the ECM circle, the trademark symbol ® and the claim "Type Approved" inside. It is reported in Picture 1 below.

The color used for all shapes is blue, the background is white, and the Europe Map is in light blue.

BLUE				GRAY				DARK BLUE			
R	8	C	95	R	178	C	0	R	0	C	100
G	95	M	38	G	178	M	0	G	32	M	67
B	154	Y	0	B	178	Y	0	B	96	Y	0
HTML	085f9a	K	40	HTML	b2b2b2	K	30	HTML	002060	K	62



Picture 1

The *Mark* is a registered trademark and cannot be changed either in form, colour or content. Its dimensions can be changed, but keeping the same proportions of Picture 1 above. In particular, dimensions of the voluntary *Mark*, if reported beside the CE mark or the logo of the holder of the *Mark*, must not be bigger than these two.

Although similar, ECM logo differs from ECM voluntary *Mark*: the former can be used only by ECM in its documentation, in its paper and digital publications, both for advertising and official and binding purposes, whereas the voluntary *Mark* can be used only by the holder of the *Mark*.

In Picture 2 below, comparison between ECM logo and ECM voluntary *Mark* are reported.

ECM LOGO	VOLUNTARY MARK
	

Picture 2

9. CRITERIA TO ASK ECM FOR VOLUNTARY *MARK* RELEASE AND PROCESS TO OBTAIN IT

The certificates are issued by ECM on a voluntary basis and upon request. They are issued with reference to a product and after review by ECM of its technical file (test reports, documentation, user manual); they are issued only if, to an ECM technitian standpoint, the technical file is compliant to the essential requirements of the Directives applicable to such a kind of product.

The release process of the voluntary *Mark* by ECM is made up of the following steps:

1. first, the documentation review
2. then, at the end of the documentation review, a positive assessment of the reviewer
3. finally, the decision of the person identified inside ECM organization as approver of releasing the *Mark*.

Note: The technical requirements are related to the physical properties of the product and not to its production or to the legal requirements of the directives.

ECM does not assume and cannot assume any obligation to a positive outcome of that assessment and, consequently, to issue the relevant certification.

10. RESPONSIBILITIES AND RIGHTS

10.1. RESPONSIBILITY OF THE MANUFACTURER

The product is under manufacturer responsibility.
Since many Directives require the use of a Notified Body to state the compliance of a product, it is under responsibility of the manufacturer or its representative in Europe to fulfill requirements of the proper Directive and to involve a Notified Body whenever required.
It is under manufacturer responsibility as well to be in compliance with the requirements of the law with regards to CE mark application.

10.2. RESPONSIBILITY AND RIGHTS OF THE HOLDER OF THE *MARK*

As general reference, the holder of the *Mark* must keep the Technical Documentation and is responsible for the Technical File.
The holder of the *Mark* must adapt to the requirements mentioned in the Directives.
The holder of the *Mark* is the only one responsible of its usage.
The holder of the *Mark* (or its employees):

- must use the *Mark* according to the rules reported in paragraph 7 of this Regulation
- in general, must behave and act in compliance with the rules of this Regulations;
- must provide ECM with all technical documentation, in Italian or in English, necessary to start the process of release of voluntary *Mark* according to instructions reported in paragraph 9 of this Regulation
- must promptly communicate ECM any changes impacting the product the *Mark* refers to
- must promptly communicate to ECM any complaints raised by customers on the product the Mark refers to
- must keep updated all the documentations required by ECM;
- must inform ECM of any change of location and address, of any new office and/or branches started by the Holder itself, change of Holder's name and any other relevant changes
- cannot use the *Mark* in such a way to induce the end user to understand a partnership of the holder of the Mark with ECM as Notified Body. The role of the Notified Body ECM must not be affected by the use of the *Mark*. For instance, the mark cannot be combined with the ECM logo and with the statement "let's be your partner"
- cannot allow others to use the *Mark* on behalf of the holder itself
- cannot associate to the *Mark* any slogan of the holder of the *Mark*
- cannot combine the *Mark* with any other logo or trademarks that may change its meaning or be misunderstood by the end user
- restrict the usage of the voluntary certificates to experts of CE marking that are familiar with such a kind of certificates. Certificates cannot have a general use, to keep as low as possible the risk of misunderstanding by inexpert people
- can never associate the voluntary *Mark* with ACCREDIA mark, that can be used only by organizations certified by an accredited party
- after suspension, revocation or renouncement of the *Mark*, must stop usage of all commercial, advertising and promotional materials that make reference to it
- if the scope of the *Mark* is reduced for whatever reason, must amend all commercial, advertising and promotional materials that make reference to it

- must ensure that all possible end users of commercial, advertising and promotional materials that make reference to the *Mark* do not misunderstand the scope of the *Mark*, thinking that it is applicable to products or activities out of the actual scope of the *Mark*
- cannot use the *Mark* in a way that could damage the reputation of ECM and compromise trust of all possible ECM stakeholders
- must be available for any supplementary verification requests of ECM.

The holder of the *Mark* can (rights):

- use the *Mark* under conditions and according to the rules mentioned in this document. This right is no longer valid after the expiration date of the certificate
- can place the Mark on the product where foreseen;
- use the *Mark* for internal (inside the holder's company) or external use, applying it:
  - on the documentation accompanying the product that received the *Mark*;
  - on the commercial, advertising and promotional documentation related to the product that received the *Mark*;
  - on company presentations both for internal use and for sales purposes;
  - on exhibition stands where the product that received the *Mark* is presented;
  - in press release;
  - in information campaigns related to the product which obtained the *Mark*, addressed to the company and the sales network
- communicate ECM its level of satisfaction, including any complaints (in writing) so as to allow ECM improve the supplied service
- complain (in writing) on ECM comments raised during the evaluation process of compliance

10.3. RESPONSIBILITY AND RIGHTS OF ECM

ECM must:

- start an investigation on any complaint or notice from the market, according to instructions reported in paragraph 15 of this Regulation and, if found acceptable, the certificate will be withdrawn
- manage each *Mark* file, from the receipt of the request of Mark, to its issuance and subsequent updates;
- apply the regulations shown for what ECM is concerned
- if officially informed, communicate to the competent Authorities (if applicable) cases in which companies, holding the Mark, are involved in legal proceedings on the responsibility of damaging products on safety;
- reject an application for Mark if suspects a risk for impartiality over the acceptance limit
- inform the Supervisory Authority of the market (where applicable) about the facts and situations that could affect the safety of the consumer because of the use of a marked product (ECM webpage there a section to verify the authenticity of the *Mark* is available.
- in case ECM should discover a false Mark, ECM itself will publish the document on its website (see "fake certificates" section) and decide whether to report them to the judicial authorities.

ECM can use both employees and freelance experts, to carry out the activities to release the voluntary *Mark*.
The product, its production, importation, distribution, sale, advertising, technical assistance or consultancy on it, or acting as a trustee are not under ECM responsibility.
ECM is NOT responsible of any CE mark of the product shown on the certificate.

11. ARCHIVING OF TECHNICAL FILES

ECM is NOT responsible of archiving of the manufacturer's technical files.
Generally, the manufacturer's technical file is NOT stored either at EMC site or in EMC database after release of voluntary Certificate/ *Mark*.
It is under manufacturer's responsibility to keep the documents available to the Authorities.
Note: The technical file MUST be stored in Europe.

12. VALIDITY AND RENEWAL OF THE CERTIFICATE

The *Mark* shelf life is specified in the voluntary certificate. A three (3) years shelf life is always associated to it. If, during the shelf life of the *Mark,* the manufacturer make changes on to the involved product, the *Mark* is immediately no longer valid.
When the expiry date is reached, the holder of the *Mark* can choose to keep it or not:

- the customer that decides to stop its holding is obliged to remove any reference to it from any kind of material it was applied to
- to prolong the shelf life of the Mark (3 years more), ECM has to carry out a new evaluation, applying the procedure reported in paragraph 9.

13. RENOUNCING

In any moment the holder of the *Mark* can ask to renounce to it, by means of a written request sent to ECM.

14. WITHDRAWAL (SUSPENSION) OF CERTIFICATES AND OF THE AUTHORIZATION TO USE THE MARK

The certificates are withdrawn

- whether there are evidences that the product does no longer comply with requirements of the reference Directive
- whether there are evidences that the product changed after the release of the *Mark*
- lack of communication of any variations of the company name or change of company location;
- whether this regulation is not applied by the holder of the mark
- Possible changes of the requirements of the reference Directives (taking into account timing allowed by regulation itself to comply with the new requirements)
- Notification of detection on the product by Authorities of any non conformities with regards to the essential requirements of the reference Directives

15. COMPLAINTS, APPEALS AND PROTESTS

15.1. INTRODUCTION

15.2. COMPLAINTS

ECM takes into account and manages both written and verbal complaints from any stakeholders.
ECM does not take into account any complaints in anonymous form, even if written.
The Director of Services and his/her staff perform a first analyses of the complaint, to understand whether or not it is founded. Management process:

- unfounded complaints → Director of Services or his/her staff or the Sales personnel get in touch with whom sent the complaint, to inform the stakeholder of the output of this first assessment and close the complaint/notice file;
- founded complaints → ECM identifies 2 categories:
  1. the root cause analysis of the complaint/notice leads to identify, as root cause, ECM administrative, procedural, and/or ethical inadequacy in carrying out the activities to release the *Mark*. The complaint is managed by ECM Director of Services or his/her staff together with ECM QA personnel. The root cause analysis is carried out relying on information provided by the sender, according to the internal procedures of ECM on complaints management. After root cause identification, the necessary CAPAs are implemented by ECM. As containment action, the Director of Services of ECM submits the review of the *Mark* to a technician/team who did not take part to the initial procedures that led to the release of the *Mark*. The results is then evaluated by the person in charge of the release of the *Mark* (see paragraph 9). The output of the complaint management can even be the suspension of the voluntary certificate;
  2. the root cause analysis of the complaint/notice leads to identify a non-compliance the sample involved in the complaint (due for instance to deficiencies of the manufacturing process or due to installation mistakes). In such a case, there is automatically the suspension of the *Mark* by ECM. ECM sends to whom sent the complaint/notice and the manufacturer a written communication containing, among the others, the list of corrective measures to be implemented by the manufacturer itself and a schedule of ECM to verify of site its implementation. The sender of the complaint can at any time asks QA the progress status of the complaint management. The possibility to inform other people / organizations out of the ones mentioned before is evaluated by ECM, together with whom sent the complaint and all other possible stakeholders.

15.3. CLAIMS OR APPEALS

Claims against decisions or documents released by ECM must be presented in writing by means of ordinary post, fax or certified email not later than 15 days from the reception of the act against which an entity is going to appeal to. ECM confirms to take into account the claim not later than 5 working days from its reception and, if required in writing, takes care of keeping informed the sender.
All claims are recorded in a register.
If the claim refers to administrative – economic aspects, the review is carried out by the ECM Sales Department and and QA personnel. The acceptance or not of the claim is

communicated by ECM legal representative to the sender by means of certified post, not later than 60 days from the receipt.
If, on the other hand, the claim refers to technical procedures of release of the *Mark*, Director of Services of ECM submits the review of the *Mark* to a technician/team who did not take part to the initial procedures that led to the release of the *Mark*. The results is then evaluated by the person in charge of the release of the *Mark* (see paragraph 9). ECM legal representative communicates the sender the result of the approval or not and, hence, acceptance or not of the claim not later than 90 days from the receipt.

16. CONTROVERSIES

Exclusively the Court of Bologna is responsible to handle with any controversy.

17. PRIVACY

All documents, letters, communications etc. related to the voluntary *Mark* activities on products belonging to the manufacturer are considered private. Access to their consultation is allowe only to those involved in the certification procedure specifically on that product.

18. DECLARATION OF DOCUMENTATION REVIEW

ECM can release, once again on voluntary basis and if required by the customer, a document that states the compatibility of the documents of any non sterile, class I Medical Devices Manufacturer with the European standard specific for such a kind of products (93/42/CEE Directive, Annex VI).
The release of this declaration does not change any responsibilities of the Manufacturer with regards to CE marking process: such a kind of declaration does not mean that the Manufacturer can skip any of the compliance steps required by this process.