

Certification of Substances Division

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Certification of suitability to Monographs of the European Pharmacopoeia

**Guideline on Requirements for Revision/Renewal of Certificates
of Suitability to the European Pharmacopoeia monographs**

**GUIDELINE ON REQUIREMENTS FOR REVISION/RENEWAL OF
CERTIFICATES OF SUITABILITY
TO THE EUROPEAN PHARMACOPOEIA MONOGRAPHS**

Table of Content

Introduction	p. 3
Notifications	p. 4
Immediate Notifications	p. 4
Notifications with annual reporting	p. 7
Notifications for TSE certificates of suitability	p. 13
Typical minor changes for certificates for chemical purity	p. 15
Major changes	p. 18
Renewal	p. 19
Transfer of holdership	p. 19

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Introduction:

The holder of a Certificate of suitability shall inform the EDQM of any change to the information in the certification dossier by sending an application form and all necessary documents demonstrating that the conditions laid down in the present guideline are met.

Classification of changes

The changes have been classified in three categories (notification/minor/major) depending on the potential impact of the change on the quality of the final substance. These three categories are based on those (IA-IA_{IN}/IB/II) of the Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisation for medicinal products for human use and veterinary medicinal products.

Any change not classified as a notification or a major change should be classified as a minor change except in the following cases where a new application should be submitted:

- addition of a new route of synthesis and/or a new manufacturing site where the specifications of the final substance are different from the one already approved
- transfer to a new holder that is not the same legal entity as the approved one, where the transfer does not occur because of a merger or because the company is sold, and where the manufacturer does not take out the Certificate of suitability in their own name.

The changes related to Ph. Eur. monograph revisions or any other regulatory requirements are treated separately and generally initiated by the EDQM.

Documentation to be provided

For any revision the documentation should consist of:

- a cover letter
- the application form, duly filled and listing all the changes applied for
- a description of each change together with a justification
- data showing, when applicable, that the conditions have been met
- update of the relevant section(s) of the dossier (presented in EU-CTD format).
- the specific documents described below for each change and supporting the change
- supportive information, including comparative data with the previous version of the dossier (in tabular format), showing the approved and the proposed section and highlighting the changes

Consequential changes should be identified and the relation between the changes should be described.

Each time batch data are needed:

- they should be in accordance with the specifications of the current Ph. Eur. monograph and when relevant with the additional requirements included in the Certificate of suitability
- the manufacturing site, the manufacturing date and the size of the batches should be specified.

- quantitative results should be presented numerically (i.e. not in general terms such as “complies”) and with the appropriate number of decimal places.

The changes are presented in five sections:

- Notifications (N and T)
- Typical minor revisions for Certificates of suitability for chemical purity and microbiological quality or for TSE Certificates of suitability
- Major revisions (MAJ)
- Renewal
- Transfer of holdership

Editorial changes should not be submitted as separate variations but should be reported at the same time as changes concerning the respective part of the dossier. In any case, a declaration should be provided that the content of the concerned part of the dossier has not been changed by the editorial changes (except for the change itself).

NOTIFICATIONS (IN/AN)

Notifications are split into *immediate* notifications and notifications *with annual reporting*.

1. Immediate notifications (IN):

IN₁) Change in the name and/or address of the certificate holder of the final substance (former N1)

Conditions:

- the certificate holder shall remain the same legal entity (except where the company is sold or in case of a merger).

Specific Documentation:

- a formal document from a relevant official body (e.g. Chamber of Commerce) in which the new name or the new address is mentioned
- all updated declarations (annexes to the application form).

IN₂) Change in the name and/or address of the manufacturing site for the final substance (former N2)

Conditions:

- the location of the manufacturing site shall remain the same.

Specific Documentation:

- a formal document from a relevant official body (e.g. Chamber of Commerce) in which the new name or the new address is mentioned
- updated declarations of manufacture in accordance with the dossier and according to GMP rules and of willingness to be inspected.

IN₃) Deletion of any manufacturing site for the final substance (former N3)

Conditions:

- the deletion should not be due to critical deficiencies concerning manufacturing.

Specific Documentation:

- the justification of the deletion.

IN₄) Change or addition of a manufacturer of a starting material or intermediate used in the manufacturing process of the final substance when the proposed manufacturer is part of the same group as the currently approved manufacturer

Conditions:

- the specifications and the route of synthesis (including In-Process Controls, methods of analysis of all materials used) of the concerned material are identical to those already approved
- the final substance is not a biological substance or a sterile substance.

Specific Documentation:

- a declaration from the holder of the Certificate of suitability that the specifications of the final substance are the same as those already approved
- a declaration from the holder of the Certificate of suitability that the synthetic route (or in case of herbal material, where appropriate, the method of preparation, geographical source and production), the specifications and the quality control procedures of the starting material or intermediate are the same as those already approved
- a list of approved and proposed sites
- batch analysis data (in a comparative tabular format) for at least two batches (minimum pilot scale) of the final substance from the approved and proposed sites.

IN₅) Change or addition of a manufacturing site/workshop for the final substance when the proposed manufacturer is part of the same group as the currently approved manufacturer

Conditions:

- the specifications of the final substance (including in process controls, methods of analysis of all materials), method of preparation (including batch size) and detailed route of synthesis are identical to those already approved
- the final substance is not a biological substance or a sterile substance.

Specific Documentation:

- a declaration from the holder of the Certificate of suitability that the synthetic route (or in case of herbal material, where appropriate the method of preparation, geographical source and production), quality control procedures and specifications of the final substance are the same as those already approved

- a list of approved and proposed sites
- batch analysis data (in a comparative tabular format) for at least two batches (minimum pilot scale) of the final substance from the approved and proposed sites
- updated declarations of manufacture in accordance with the dossier and according to GMP rules and of willingness to be inspected for the new site.

IN₆) Tightening of the specification limits for the final substance (former N8)

Conditions:

- the change does not result from unexpected events arising during manufacture
- any change should be within the range of currently approved limits
- the test procedure remains the same, or changes in the test procedure are minor.

Specific Documentation:

- comparative table of approved and proposed specifications.

IN₇) Minor changes to a test procedure for the final substance. Editorial changes to a method description annexed to a certificate of suitability (former N7)

Conditions:

- appropriate validation studies have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure
- there have been no changes of the total impurity limits; no new unqualified impurities are detected
- the method of analysis should remain the same (e.g. a change in column length or temperature, but not a different type of column or method)
- the test method is not a biological method, or a method using a biological reagent for a biological substance (does not include standard pharmacopoeial microbiological methods).

Specific Documentation:

- updated description of the method in a format to be appended to the certificate of suitability
- amendment of the relevant section(s) of the dossier, including description of the analytical method, summary of validation data,..
- comparative validation results, or if justified comparative analysis results showing that the approved test and the proposed one are equivalent.

IN₈) Addition of a specification parameter for the final substance

Conditions:

- the change does not result from unexpected events arising during manufacture
- any new test method does not concern a novel non-standard technique or a standard technique used in a novel way
- the test method is not a biological method or a method using a biological reagent for a biological substance (does not include standard pharmacopoeia microbiological methods)
- the change does not concern a genotoxic impurity

Specific Documentation:

- comparative table of approved and proposed specifications
- details of any new analytical method and validation data, where relevant
- batch analysis data on two production batches of the relevant substance for all specification parameters.

IN₉) Removal/reduction of the re-test period from the Certificate of suitability / change to more restrictive storage conditions (former N11)

Conditions:

- the change should not be the result of unexpected events arising during manufacture or because of stability concerns

Specific Documentation:

- the justification of the removal/reduction of the re-test period

IN₁₀) Deletion of an approved change management protocol for design space submission

Conditions:

- the deletion of the approved change management protocol is not a result of unexpected events or out of specification results during the implementation of the change (s) described in the protocol.

Specific Documentation:

- amendment of the relevant section(s) of the dossier

2. Notification with annual reporting (AN):

AN₁) Change in the name and/or address of a manufacturer of a starting material or intermediate used in the manufacture of the final substance

Conditions:

- the location of the manufacturing site shall remain the same

Specific Documentation:

- updated list of manufacturers of starting material/intermediate

AN₂) Deletion of a manufacturer of a starting material/intermediate used in the manufacture of the final substance (former N4)

Conditions:

- the deletion should not be due to critical deficiencies concerning manufacturing

Specific Documentation:

- the justification of the deletion
- updated list of manufacturers of starting material/intermediate

AN₃) Change in the code product/reference number and/or in the brand name of the final substance or any material used in its manufacture (former N9)

Condition:

- the change does not regard the quality of the final substance or the concerned material

Specific Documentation:

- approved and proposed code product / reference number / brand name

AN₄) Minor change in the manufacturing process of the final substance (former R1)

Conditions:

- the specifications of the final substance or intermediates are unchanged and there is no adverse change in qualitative and quantitative impurity profile
- the synthetic route remains the same, i.e. intermediates remain the same and there are no new reagents, catalysts or solvents used in the process. In the case of herbal products, the geographical source and production of the herbal material remain unchanged
- the final substance is not a biological substance.

Specific Documentation:

- batch analysis data (in comparative tabular format) of at least two batches (minimum pilot scale) manufactured according to the currently approved and proposed process.

AN₅) Change in batch size of final substance or intermediate up to 10-fold compared to the original batch size (former N5)

Conditions:

- any changes to the manufacturing methods are only those necessitated by scale-up, e.g. use of different-sized equipment
- test results of at least two batches of the final substance complying with the approved specifications should be available for the proposed batch size
- the substance is not a biological substance or a sterile substance
- the change does not affect the reproducibility of the manufacturing process
- the specifications of the final substance/intermediates remain the same
- the currently approved batch size was not approved via a notification

Specific Documentation:

- the batch numbers of the tested batches having the proposed batch size
- approved and proposed batch size
- updated description of the full process specifying the proposed batch size
- a declaration from the certificate holder that the changes to the manufacturing methods are only those necessitated by scale-up, that the change does not adversely affect the reproducibility of the process, and that the specifications of the final substance/intermediates remain the same.

AN₆) Change in batch size of final substance or intermediate: downscaling (former N6)

Conditions:

- any changes to the manufacturing methods are only those necessitated by the downscaling, e.g. use of different-sized equipment
- test results of at least two batches of the final substance complying with the approved specifications should be available for the proposed batch size
- the substance is not a biological substance or a sterile substance
- the change does not affect the reproducibility of the manufacturing process
- the change should not be the result of unexpected events arising during manufacture or because of stability concerns
- the currently approved batch size was not approved via a notification.

Specific Documentation:

- the batch numbers of the tested batches having the proposed batch size
- approved and proposed batch size
- updated description of the full process specifying the proposed batch size
- a declaration from the certificate holder that the changes to the manufacturing methods are only those necessitated by downscaling, that the change does not adversely affect the reproducibility of the process, that it is not the result of unexpected events arising during manufacture or because of stability concerns and that the specifications of the final substance/intermediates remain the same.

AN₇) Addition of a new in-process test and limit applied during the manufacture of the final substance

Conditions:

- the change does not result from unexpected events arising during manufacture
- any new test method does not concern a novel non-standard technique or a standard technique used in a novel way
- the new test method is not a biological method or a method using a biological reagent for a biological substance (does not include standard pharmacopoeial microbiological methods).

Specific Documentation:

- comparative table of approved and proposed in-process tests
- details of any new non-pharmacopoeial analytical method and validation data, where relevant.

AN₈) Deletion of a non significant in-process test applied during the manufacture of the final substance

Conditions:

- the change does not result from unexpected events arising during manufacture.

Specific Documentation:

- comparative table of approved and proposed in-process tests
- justification /risk-assessment from the certificate holder as appropriate showing that the parameter is non-significant.

AN₉) Tightening of the limits of in-process tests applied during the manufacture of the final substance

Conditions:

- the change does not result from unexpected events arising during manufacture
- the test procedure remains the same, or changes in the test procedure are minor.

Specific Documentation:

- comparative table of approved and proposed in-process tests.

AN₁₀) Addition of a specification parameter for a starting material/intermediate/reagent

Conditions:

- the change does not result from unexpected events arising during manufacture
- any new test method does not concern a novel non-standard technique or a standard technique used in a novel way

- the test method is not a biological method or a method using a biological reagent for a biological substance (does not include standard pharmacopoeia microbiological methods).

Specific Documentation:

- comparative table of approved and proposed specifications
- details of any new analytical method and validation data, where relevant.

AN₁₁) Deletion of a non-significant specification parameter for the final substance/starting material/intermediate or deletion of a test procedure for a starting material/intermediate/reagent

Condition:

- the change does not result from unexpected events arising during manufacture
- the parameter is non-significant or an alternative test procedure is already approved.

Specific Documentation:

- comparative table of approved and proposed specifications
- justification/ risk-assessment from the holder of the certificate as appropriate showing that the parameter is non-significant.

AN₁₂) Minor changes to a test procedure for a starting material/intermediate/reagent used in the manufacturing process of the final substance (former N7)

Conditions:

- the method of analysis should remain the same (e.g. a change in column length or temperature, but not a different type of column or method)
- appropriate (re-)validation studies have been performed in accordance with relevant guidelines and show that the new updated test procedure is at least equivalent to the former one
- the final substance is not a biological substance.

Specific Documentation:

- updated method description.

AN₁₃) Tightening of the specification limits for a starting material/intermediate/reagent used in the manufacturing process of the final substance (former N8)

Conditions:

- the change should not be the result of unexpected events arising during manufacture
- any change should be within the range of currently approved limits
- the test procedure remains the same, or changes in the test procedure are minor.

Documentation

- comparative table of approved and proposed specifications.

AN₁₄) Change in the composition of the immediate packaging

Conditions:

- the proposed packaging material must be at least equivalent to the approved material in respect of its relevant properties
- relevant stability studies have been started under ICH conditions and relevant stability parameters have been assessed in at least two pilot scale or industrial scale batches and at least three months satisfactory stability data are at the disposal at time of implementation.

NB: if the proposed packaging is more resistant than the existing packaging, the three months stability data do not yet have to be available.

These studies must be finalized and the data will be provided immediately to EDQM if outside specifications or potentially outside specifications at the end of the re-test period (with proposed action).

- the final substance is not a sterile, liquid or biological substance.

Specific Documentation:

- comparison of the approved and proposed immediate packaging specifications, if applicable
- appropriate data on the new packaging including a confirmation that the material complies with relevant pharmacopoeial requirements or EU legislation on plastic materials and objects in contact with foodstuffs
- a declaration from the holder of the certificate as appropriate that the required stability studies have been started under ICH conditions (with indication of the batch numbers concerned) and that, as relevant, the required minimum satisfactory stability data were at the disposal at time of implementation and that the available data did not indicate a problem. Assurance should also be given that the studies will be finalized and that data will be provided immediately to the competent authorities if outside specifications or potentially outside specifications at the end of the approved re-test period (with proposed action).

AN₁₅) Change in the specification parameters and/or limits of the immediate packaging of the final substance

Conditions:

- the change does not result from unexpected events arising during manufacture of the packaging material or during storage of the final substance
- the test procedure remains the same, or changes in the test procedure are minor
- any new test method does not concern a novel non-standard technique or a standard technique used in a novel way.

Specific Documentation:

- comparative table of approved and proposed specifications.

NOTIFICATIONS FOR TSE CERTIFICATES (TIN/TAN)

1. Immediate notifications (TIN):

TIN₁) Deletion of a source country or change in source of a material used in the preparation of the final substance from a TSE risk material to a vegetable, synthetic, or non-TSE risk material (former N12)

Conditions:

- no change in the manufacturing process.

Specific Documentation:

- if applicable a declaration from the certificate holder or manufacturer of the material that it is purely of vegetable, synthetic or non-TSE risk origin.

TIN₂) Change or addition of a manufacturing site for the final substance when the proposed manufacturer is part of the same group as the approved manufacturer (former T1)

Conditions:

- no change in the manufacturing process, in the materials and in the origin of the material used in the process
- no other TSE risk material is processed in the new manufacturing site.

Documentation:

- a declaration from the holder of the certificate/manufacturer that the manufacturing process is identical to that already approved
- a declaration from the holder of the certificate/manufacturer that no other TSE risk material is processed in the new manufacturing site
- updated declarations of manufacture in accordance with the dossier and according to GMP rules/quality system and of willingness to be inspected
- information on the quality assurance system (including traceability) applied in the new manufacturing site.

TIN₃) Change in the quality assurance system applied in the manufacturing site (Former T3)

Conditions:

- the new quality assurance system is at least equivalent to the former one
- no change in the manufacturing process (including process parameters) or in the specifications of the final substance.

Documentation

- updated information on the quality assurance system (including traceability)
- updated declarations of manufacture in accordance with the dossier and according to GMP rules/quality system and of willingness to be inspected.

2. Notifications with annual reporting (TAN):

TAN₁) Minor change in the manufacturing process (including process parameters) or in the specifications of the final substance (Former T2)
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Conditions:

- the change has no impact on the TSE risk
- the certificate of suitability covers only the TSE risk and does not cover the chemical purity and microbiological quality.

Documentation:

- comparison of the approved and proposed process
- a declaration from the holder of the certificate/manufacturer that the change has no impact on the TSE risk.

TYPICAL MINOR CHANGES FOR CERTIFICATES FOR CHEMICAL PURITY AND MICROBIOLOGICAL QUALITY

THIS IS A NON EXHAUSTIVE LIST OF MINOR CHANGES INTENDED TO HELP THE SUBMISSION AND THE PREPARATION OF THE DOCUMENTATION.

Change in batch size of the final substance or an intermediate more than 10-fold compared to the original batch size (former R2)

Specific Documentation:

- updated description of the full process specifying the new batch size
- batch analysis data (in comparative tabular format) on a minimum of one production batch manufactured according to both the approved and the proposed sizes.

Change or addition of a manufacturer of a starting material or intermediate used in the manufacturing process of the final substance

Specific Documentation:

- a declaration from the holder of the Certificate of suitability that the synthetic route (or in case of herbal material, where appropriate the method of preparation, geographical source and production), the specifications and the quality control procedures of the starting material or intermediate are the same as those already approved
- a list of approved and proposed sites
- for a manufacturer of intermediate, declarations of manufacture in accordance with the dossier and according to GMP rules and of willingness to be inspected for the proposed site
- batch analysis data (in comparative tabular format) on a minimum of one production batch manufactured with the approved and the proposed sources of material.

Change or addition of a manufacturing site/workshop for the final substance

Specific Documentation:

- a declaration from the holder of the Certificate of suitability that the synthetic route (or in case of herbal material, where appropriate the method of preparation, geographical source and production), quality control procedures and specifications of the final substance are the same as those already approved
- a list of approved and proposed sites
- updated declarations of manufacture in accordance with the dossier and according to GMP rules and of willingness to be inspected for the proposed site

- batch analysis data (in comparative tabular format) on a minimum of one production batch manufactured in both the approved and the proposed sites.

For a “double” Certificate of suitability (for chemical purity and microbiological quality and for TSE risk), change in source of a material used in the preparation of the final substance from a TSE risk material to a vegetable, synthetic, or non-TSE risk material (former R5)

Specific Documentation:

- updated specifications of the proposed source of the material
- batch analysis data (in a comparative tabular format) for at least two batches (minimum pilot scale) of the final substance from the approved and proposed source of the material or intermediate
- a declaration from the manufacturer of the material that it is purely of vegetable, synthetic or non-TSE risk origin (specifying the origin)
- a declaration from the holder of the certificate that there is no change in the manufacturing process and that the specifications of the final substance remain the same.

Extension/addition of the re-test period of the final substance and/or change in the storage conditions for the final substance (former R7)

Specific Documentation for addition of a re-test period:

- results of long-term and accelerated stability studies for at least two pilot or production scale batches
- appropriate data on the packaging material including a confirmation that the material complies with relevant pharmacopoeial requirements or EU legislation on plastic materials and objects in contact with foodstuffs.

Specific Documentation for an extension of the re-test period / change in the storage conditions for the final substance:

- updated results of stability studies for at least two pilot or production scale batches.

Change/addition of a manufacturer of starting material/intermediate used in the manufacturing process of a biological substance

Specific Documentation:

- a declaration from the holder of the certificate that the manufacturing process, quality control procedures and specifications of the final substance and of the concerned material are the same as those already approved
- a list of approved and proposed sites

- for a manufacturer of intermediate, declarations of manufacture in accordance with the dossier and according to GMP rules and of willingness to be inspected for the proposed manufacturer
- batch analysis data (in comparative tabular format) on 3 batches (minimum pilot scale) manufactured according to both the approved and the proposed manufacturers.

Change/addition of the manufacturer of a biological substance

Specific Documentation:

- a declaration from the holder of the certificate that the manufacturing process, quality control procedures and specifications of the final substance are the same as those already approved
- batch analysis data (in a comparative tabular format) for at least 3 batches (minimum pilot scale) of the final substance from the approved and the proposed sites
- updated declarations of manufacture in accordance with the dossier and according to GMP rules and of willingness to be inspected.

Minor changes in the manufacturing process of a biological substance, including change in batch size

Specific Documentation:

- a direct comparison of the approved and the proposed process
- a declaration from the holder of the certificate that the specifications of the final substance are the same as those already approved
- batch analysis data (in comparative tabular format) of at least 3 batches (minimum pilot scale) of the final substance manufactured according to the approved and proposed process or according to both approved and proposed batch sizes, demonstrating that the change has no negative impact on the quality of the final substance.

Changes to a test procedure (including replacement or addition) for the biological substance/starting material/intermediate or changes to a biological method

Specific Documentation:

- description of the analytical method, a summary of validation data
- comparative analysis results showing that the approved and the proposed test are equivalent. This requirement is not applicable in case of an addition of a new test procedure.

MAJOR CHANGES (MAJ)

MAJ1 – Change/addition of the manufacturer of a starting material or intermediate, when the proposed manufacturer uses a substantially different route of synthesis or manufacturing conditions, which are likely to change the qualitative and/or quantitative impurity profile (eg. new reagents, solvents, materials are introduced in the synthesis)

MAJ2 - Change in the manufacturing process of the final substance that regards the sterilization step(s), including changes in batch size of a sterile substance

MAJ3 - Substantial change to the manufacturing process/addition of an alternative manufacturing process for a starting material, intermediate or final substance likely to change the qualitative and/or quantitative impurity profile (eg. new reagents, solvents, materials are introduced in the synthesis)

MAJ4 - Changes in the manufacturing process of a herbal substance related to geographical source or production

MAJ5 - Widening or deletion of approved in-process test limits, which may have a significant effect on the overall quality of the final substance

MAJ6 – Widening of the approved specifications limits for the final substance

MAJ7- Widening of the approved specifications limits for starting materials/ intermediates, which may have a significant effect on the overall quality of the final substance

MAJ8 - Deletion of a specification parameter which may have a significant effect on the overall quality of the final substance

MAJ9 - Change in the composition of immediate packaging for a sterile substance

MAJ10 - Introduction of a new design space or extension of an approved design space or of a post approval change management protocol related to the final substance

TSE changes

MAJ11 – Change/addition of a source country or tissues for TSE risk material

MAJ12 - Change/addition of a manufacturer of a starting material or intermediate

MAJ13 – Change/addition of a manufacturing site where other TSE materials than the substance are processed

MAJ14 - Substantial changes in the manufacturing process that are likely to affect the TSE risk

RENEWAL

The Certificate of suitability is valid for five years from the date when the original certificate was granted. Regardless of any revisions treated in the meantime, the holder of a Certificate of suitability shall ask for the renewal of the Certificate of suitability six months prior to expiry date by providing an update of the certification dossier.

If no change has been made since the last Certificate of suitability was granted

Documentation:

- a statement that no changes that may affect the quality, safety or efficacy of the final substance have been made
- certificates of analysis from at least two recent production batches
- updated declarations as appendixes to the application form.

If changes are included in the request for renewal

Documentation:

- an updated dossier in CTD format and/or updated sections affected by the changes
- list of changes introduced in the format of a comparative table
- relevant data supporting each change as described in this guideline
- certificates of analysis from at least two recent production batches
- updated declarations as appendixes to the application form.

TRANSFER OF HOLDERSHIP OF A CERTIFICATE OF SUITABILITY

A transfer of the holdership of the Certificate of suitability (i.e. change in the name of the certificate holder that is not the same legal entity and where the change does not occur following a sale or a merger) is feasible in exceptional cases with the below conditions:

- the current Certificate of suitability is held by another company than the manufacturer
- the manufacturer takes out the Certificate of suitability in their own name.

Documentation:

- a letter signed by both parties, i.e. the former holder and the manufacturer, agreeing that the holdership of the Certificate of suitability is passed on to the manufacturer from the date of the request
- updated declarations as annex to the application form.