



MINIMUM QC REQUIREMENTS FOR RE-HOMOLOGATION PROCESS FOR FHR DEVICES ACCORDING TO FIA STANDARD 8858-2010

1. Foreword

According to the **Re-homologation process-clarification note** available on the FIA website <https://www.fia.com/regulation/category/762>, manufacturers choosing option 1 for re-homologating their products need to present to their ASN a declaration and explanation of their internal quality control system (QC). As stated in the aforementioned document, in order for the QC system to be acceptable for approval, it will need to comply with some minimum requirements. This document describes the minimum requirements of the QC system that the manufacturer will need to have in place, as well as the documentation that is necessary to provide to obtain the re-homologation.

For clarity purposes, it has been deemed useful to specify the meaning of several expressions that will be used in this document and during the assessment process:

To MAINTAIN OBJECTIVE EVIDENCE refers to the manufacturer being able to provide justification that what was planned has actually been done. It is not necessary to keep records of the actual values, but it must be possible to demonstrate that the controls have been carried out.

To RETAIN DOCUMENTED INFORMATION refers to the manufacturer keeping records of the data of the checks (with values).

To MAINTAIN DOCUMENTED INFORMATION refers to the manufacturer being able to provide justification of documented processes and controls. This could be in the form of explicative documents, but it could also be for example videos of the processes or photographs.

2. Minimum requirements

2.1 Processes control

In order for the QC system to be acceptable, the company must maintain objective evidence of the following:

- Procurement process control
- Client order review and control
- Production order review and control
- Staff training (including new staff)
- Internal audits

In addition, the company must maintain documented information of the following:

- Production processes including drawing controls and process change records
- Non-conformities management

2.2 Traceability of materials and components

The QC system must ensure that key raw materials and components for the product can be traced for each item produced. Documented information on the traceability must be retained.



Key materials are those that could directly affect the outcome of any of the tests defined in section 2.4. In the case of FHR devices according to FIA standard 8858-2010, the following groups of materials as a minimum are considered key materials:

- Fibres,
- Resins,
- Injected plastic

Given an FIA hologram number, it must be possible to identify the batches of the key raw materials used in that specific device.

2.3 Control of 100% of the product before delivery

The QC system must include some controls of each item produced. In the case of FIA standard 8858-2010, for each unit of FHR device (100% of the products) it is necessary to maintain objective evidence of the following checks:

- Visual inspection;

2.4 Random testing of components and/or final products

In order to control the final product performance, it is compulsory that the QC system includes a random checking and testing programme to confirm that the production still complies with the requirements of the standard.

For all FIA standard 8858-2010 FHR devices it is necessary to perform and retain documented information of at least the following tests:

- Geometrical dimensions:
 - 1% of the devices;
- Mechanical strength tests as defined in Art. 5.2.1 for HANS and in Art. 5.2.2 for Hybrid of the FIA standard 8858-2010:
 - 1 device every 2.5 years for productions of less than 800 devices/year;
 - 0.5‰ of the devices for productions equal or higher than 800 devices/year;
- Flame resistance tests as defined in Art. 5.3 of the standard FIA 8858-2010:
 - 1‰ of the devices;

These tests can be done internally in the manufacturer's facilities or externally. It is not necessary to use an FIA-approved test house. Variations of the mechanical strength tests can be used but only with prior approval by the FIA.



3. Documentation to be provided for re-homologation

When applying for re-homologation using option 1, the manufacturer must submit to its ASN the Re-homologation Application Template and, in order to explain and declare its QC system, it must also submit the following information, depending on whether or not the manufacturer is certified according to ISO 9001:2015.

3.1 Manufacturers not certified according to ISO 9001:2015

- Declaration, in a company letterheaded document, filled in and signed, in accordance with:
 - Appendix I Processes control;
 - Appendix II Traceability of the materials and components;
 - Appendix IV Controls performed to 100% of products;
 - Appendix V Random testing programme.
- Flow chart indicating when the controls declared in Appendix IV and Appendix V are done during the production process.

3.2 Manufacturers certified according to ISO 9001:2015

- Copy of a valid ISO 9001:2015 certificate
- Declaration, in a company letterheaded document, filled in and signed, in accordance with:
 - Appendix III Traceability of FIA hologram numbers;
 - Appendix IV Controls performed to 100% of products;
 - Appendix V Random testing programme.
- Flow chart indicating when the controls declared in Appendix IV and Appendix V are done during the production process.

4. Review and audits

During the process of assessing the re-homologation request, the FIA reserves the right to request examples of the evidence and documented information required in section 2 of this document.

In addition, and as provided for under Article 6 of the FIA Homologation Regulations for Safety Equipment, the FIA reserves the right to perform audits to confirm that the manufacturer follows the quality control, and during which the manufacturer may be requested to demonstrate the veracity of its declaration and provide justification and records of the controls requested.



Appendix I Processes control

This declaration shall be supplied on letterhead paper of the applicant company and signed (full name and position within the company required).

Mr/Ms [redacted] as [redacted] at [redacted] (the company) declares that the management of the company ensures that quality objectives have been defined and communicated throughout the company. The company follows a Quality Management System in order to ensure that production and procurement are carried out under controlled conditions and to ensure that the final product conforms to the requirements of the FIA standard for which they are homologated.

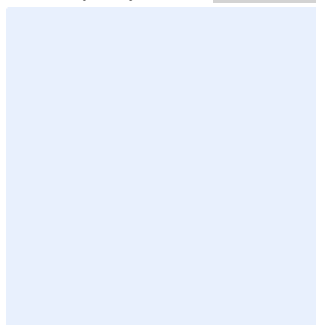
The company maintains objective evidence of the following:

- Procurement process control
The company has processes in place to ensure that the products and services incorporated in the final product and supplied externally comply with the requirements and specification of the original homologated product.
- Client order review and control
The company reviews the products that are going to be offered to customers in order to ensure that the requirements of FIA standard 8858-2010 are still complied with, and that no modification has been made with respect to the originally homologated product without authorisation by the FIA.
- Production order review and control
- Staff training (including new staff)
- Internal audits

In addition, the company maintains documented information of the following:

- Production processes, including drawing controls and process change records
- Non-conformities management

This Quality Management System has been in place in the company since [redacted]



Date: [redacted]



Appendix II Traceability of materials and components

This declaration shall be supplied on letterhead paper of the applicant company and signed (full name and position within the company required).

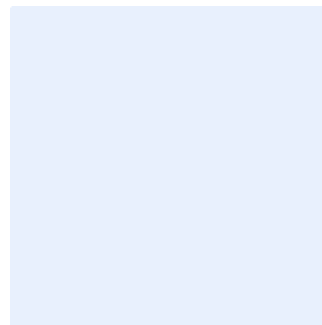
Mr/Ms [redacted] as [redacted] at [redacted] (the company) declares that the company retains documented information that allows all key materials of the products to be traced including information on the following:

- Supplier,
- Purchase date,
- Batch number,
- Controls or checks performed on arrival at the company.

It is possible to link this information to a unique identification of each product so that, given the number of the FIA hologram used on a specific device, the manufacturer is able to provide the above information on the following materials used in that specific device:

- Fibres;
- Resins;
- Injected plastic;

This traceability system has been in place in the company since [redacted]



Date: [redacted]



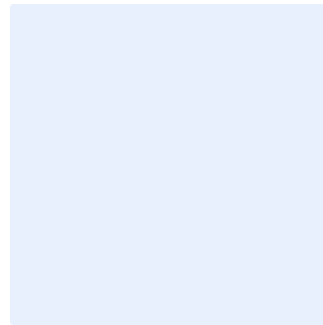
Appendix III Traceability of FIA hologram numbers

This declaration shall be supplied on letterhead paper of the applicant company and signed (full name and position within the company required).

Mr/Ms [redacted] as [redacted] at [redacted] (the company) declares that given the number of the FIA hologram used on a specific device, the company will be able to provide the batch number of the following materials used in that specific device:

- Fibres;
- Resins;
- Injected plastic;

This traceability system has been in place in the company since [redacted]



Date: [redacted]



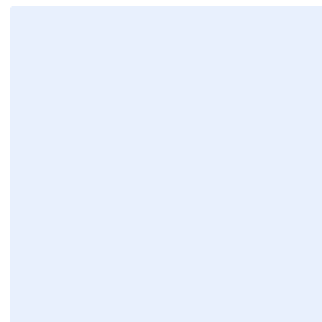
Appendix IV Controls performed on 100% of products

This declaration shall be supplied on letterhead paper of the applicant company and signed (full name and position within the company required).

Mr/Ms [redacted] as [redacted] at [redacted] (the company) declares that the below information is descriptive of the controls carried out on every FHR device produced according to FIA standard 8858-2010.

Controls	
Visual inspection	

Objective information of these controls is maintained and can be provided if necessary.
These controls have been in place in the company since [redacted]



Date: [redacted]



Appendix V Random testing programme

This declaration shall be supplied on letterhead paper of the applicant company and signed (full name and position within the company required).

Mr/Ms [redacted] as [redacted] at [redacted] (the Company) declares that the information below is descriptive of the random tests done during the production of FHR devices according to FIA standard 8858-2010.

Tests	Test	How often?	Where are the tests done?
Geometrical dimensions		devices checked every	
Mechanical strength as defined in Art. 5.2.1 for HANS and in Art. 5.2.2 for Hybrid		devices checked every	
Flame resistance tests as defined in Art. 5.3		devices checked every	

Documented information of these controls is retained and can be provided if necessary.

These controls have been in place in the company since [redacted]

[redacted] Date: [redacted]