AUDIT REPORT – LABORATORY

Wheels - Confidential

Laboratory Data:

Name:	MW ITALIA S.p.A.
Address:	Via Pavia, 72 10098 – Rivoli (TO) Italy

Audit Data:

Date:	13/01/2015
Audit Type:	☐ Initial Certification ☐ Recertification ☐ Others: ☒ Surveillance ☐ Corrective Actions Closing
Reference Documents:	☒ ISO/IEC 17025:2005 ☒ INMETRO Regulation # 445 of 11/19/2010
Scope:	☒ Steel wheels Automobile ☐ Aluminum alloy wheels Cars/ Light Trucks and SUVs ☐ Aluminum and steel wheels Trucks/busses and similar

Managerial Summary:

The Laboratory was evaluated, according to the above mentioned reference documents, and was considered:

☒ Satisfactory ☐ Unsatisfactory

Due to nonconformities found during the assessment, corrective actions must be taken according to the Nonconformity Reports (NCR) attached:

☒ Not applicable (no nonconformities found)

☐ Total of nonconformities: ___

Nonconformities closing, after assessment:

☒ Not applicable (no nonconformities found)

☐ Satisfactory (actions were implemented, see attached, nonconformities are closed)

Observations:

Cópia deste relatório fornecido à empresa.

Auditor Name:	Ing. Francesco Spinazzola	Signature:	

EVALUATION QUESTIONNAIRE

Requirements		Comments	Results
1	**CONFIDENTIALITY**		
1.1	The laboratory must have documented and implemented procedures to preserve the protection of confidentiality and integrity of information, considering, at least: a) the access to files, including computerized ones; b) restricted access to laboratory; c) knowledge of laboratory personnel on confidentiality of information.	All relevant informations are preserved and computers have rescricted access to specific area of the user (please see P.O. B01 Rev.9 procedure and quality book MQ17025 Rev.2).	**Fulfilled**
2	**ORGANIZATION**		
2.1	The laboratory must assign the signatory who will sign the test reports and bear full technical responsibility for their contents.	Laboratory assigned the signatories of testing report (please see P.O. B01 Rev.9 procedure, §4.1.5 of quality book MQ17025 Rev.2 and RDL371_14)	**Fulfilled**
2.2	Laboratory must have a technical manager and a deputy to this position (whatever its name) with global responsibility for its technical operations.	See enclosure Organigramma.	**Fulfilled**
2.3	When it is a first-party laboratory, the responsibilities of organization key-personnel that have involvement or influence on laboratory test must be defined in order to identify potential conflicts of interest.	Each key-personnel has a defined role and he is no influenced from the other colleagues. See enclosure Organigramma.	**Fulfilled**
2.3.1	It is also worthy that organizational arrays are such that the departments with potential conflict of interests, such as manufacturing, marketing, commercial or financial, do not have negative impact on laboratory compliance with the requirements hereof.	Production is detached from laboratory and no potential conflict of interest can happen. See enclosure Organigramma.	**Fulfilled**
3	**MANAGEMENT SYSTEM**		
3.1	All documents required for the correct conduction of laboratory activities must be unequivocally identified and must contain their issuance date, review number and the issuance authorization.	Documents meet the requirements (please see PO_LAB_02 proceduere)	**Fulfilled**
3.2	All the documents required for the correct development of laboratory activities shall be updated and accessible to its personnel.	Documents are available for all employees. Documents are updated and each update is sent though email to colleague using email receiving confirmation.	**Fulfilled**
3.3	The laboratory must document roles and responsibilities of the technical manager and technical personnel involved in the tests, considering, at least the responsibilities related to: a) conduction of tests; b) test planning, result review, issuance of test reports; c) modification, development, characterization, and validation of new test methods; d) managerial activities.	Roles and responsabilities are well defined. Please see Organigramma, P.O. B01 Rev.9 procedure and §4.1.5 of quality book MQ17025 Rev.2).	**Fulfilled**

Requirements		Comments	Results
3.4	The laboratory must have the identification of the authorized signatory (where this concept is appropriate).	Authorized signatories are defined in §4.1.5 of quality book MQ17025 Rev.2	**Fulfilled**
3.5	The laboratory must have documented and implemented procedures for obtaining the traceability of measurements.	Measurements are traced and results/testing reports are recorded in electonic format	**Fulfilled**
3.6	The laboratory must have formalized the range of its services and provisions to assure that has the appropriate resources and facilities.	Please see P.O. B01 Rev.9 procedure and DI_LAB_08 Rev.0.	**Fulfilled**
3.7	The laboratory must have documented and implemented procedures for handling test items.	Please see §5.8 of quality book MQ17025 Rev.2	**Fulfilled**
3.8	The laboratory must have the listing of equipment and reference standards used, including their respective identification.	Equipment are listed and monitored through "Gage Management" SW. Reference standards are recorded on server and PO_LAB_7 procedure describes how to manage them.	**Fulfilled**
3.9	The laboratory must have implemented and documented procedures for feedbacks and corrective actions, whenever tests detect non-compliances.	Please see §4.11 of quality book MQ17025 Rev.2.	**Fulfilled**
4	**PERSONNEL**		
4.1	The laboratory must have enough personnel, with the required instruction, training, know-how and expertise for the assigned roles.	Expertise and qualified personnel. Please see §4.1.5 of quality book MQ17025 Rev.2	**Fulfilled**
4.2	The laboratory must have procedures for the use of technicians in established training processes, determining, for so, the supervision records for them, and creating mechanisms for assuring that their use does not impair test results.	Please see DI_LAB_05 and DI_LAB_30 procedures. Training processes are performed.	**Fulfilled**
4.3	The laboratory must have and keep updated records of all its technical personnel involved in tests. Such records must have the date of the authorization, at least, for: a) conducting different types of sampling, when applicable; b) conducting the different types of tests; c) signing test reports; and d) operating the different types of equipment.	Please see DI_LAB_05 and DI_LAB_30 procedures and §4.1.5 of quality book MQ17025 Rev.2.	**Fulfilled**
5	**FACILITIES AND ENVIRONMENTAL CONDITIONS**		
5.1	The laboratory facilities, test areas, energy sources, illumination and ventilation must enable the proper conduction of tests.	Test areas and facilities meet the requirements and are proper for test conduction. Please see planimetry DI_LAB_34.	**Fulfilled**
5.2	The laboratory must have facilities with effective monitoring, control and record of environmental conditions, whenever required.	Test conditions are monitored, controlled and recorded if required.	**Fulfilled**
5.3	The laboratory must maintain an effective separation between neighboring areas, whenever incompatible activities are conducted.	Please see planimetry DI_LAB_34.	**Fulfilled**
6	**EQUIPMENT AND MATERIAL REFERENCES**		
6.1	The laboratory must have all the equipment, including the reference material required for correct conduction of tests.	Equipments and reference material are proper for test conduction.	**Fulfilled**

Requirements		Comments	Results
6.2	Before conduction of tests, the laboratory must check whether any equipment item is presenting suspect results. In case it occurs, the equipment must be put out of operation, identified as out of use, repaired, and evidenced through calibration, reviewing or testing to have returned to satisfactory operation before it can be put in use again.	Equipments and instruments are verified before test beginning. Please see §5.5 of quality book MQ17025 Rev.2. Equipments and instruments are calibrated and identified. They are put out of work in case of suspect results. Please see §5.5.7 of quality book MQ17025 Rev.2.	**Fulfilled**
6.3	Each equipment must be labeled, marked or identified, in order to indicate the calibration status. Such calibration status must visibly indicate the last and the next calibration.	Each equipment is labelled and the label shows equipment-ID and calibration status (expiring date of calibration).	**Fulfilled**
6.4	Each equipment must have a record indicating at least: a) equipment name; b) manufacturer name; type identification, serial number, or other specific identification; c) receiving condition, where appropriate; d) copy of manufacturer instructions, when appropriate; e) calibration and/or review dates and results, and date of next calibration and/or review; f) details of the maintenance conducted and planned for future; g) history of every damage, change or repair.	All equipments are recorded and managed through software "Gage Management" ver.8.00 [Tecnologie & Servizi devoloper]	**Fulfilled**
6.5	Each reference material must be labeled or identified, in order to indicate the certification or standardization. The label must contain, at least: a) reference material number; b) responsible for certification or standardization (company or person); c) composition, when applicable; d) expiration date.	Labels fulfill the requirements.	**Fulfilled**
7	**TRACEABILITY OF MEASUREMENTS AND CALIBRATIONS**		
7.1	The laboratory must have an established program for calibration and review of its equipment, in order to assure the use of calibrated and/or reviewed equipment at the moment test is to be conducted.	Equipments are controlled using software "Gage Management" ver.8.00 [Tecnologie & Servizi devoloper]. Each of them has an own calibration program.	**Fulfilled**

Requirements		Comments	Results
7.2	The calibration certificates for the reference standards must be issued by: a) national metrology laboratories; b) calibration laboratories accredited by Cgcre/Inmetro; c) laboratories integrating National Institutes of Metrology in another countries, in the following cases: • when traceability is obtained directly from an institution that has the primary standard of greatness associated; or • when the institution participates in inter-laboratory comparison programs, along with Cgcre/Inmetro, obtaining compatible results; • laboratories accredited by Accreditation Bodies from other countries, provided there is a mutual acknowledgement or co-operation agreement between Cgcre/Inmetro and such bodies.	Calibration certificates issued by national metrology laboratories and internal calibration related to national/international standards. Calibration certificates and internal calibration records are attached.	**Fulfilled**
7.3	The measurement and test equipment certificates of laboratory must meet the requirements in the previous item.	Calibration certificates and internal calibration records are attached.	**Fulfilled**
7.4	The reference standards kept the laboratory has must be used only for calibrations, unless it is possible to show that its performance as reference standard is not invalidated.		**Fulfilled**
8	**CALIBRATION AND TEST METHOD**		
8.1	All the instructions, rules and reference data pertinent to laboratory work must be documented, kept updated and readily available for laboratory personnel.	All relevant instructions, rules and reference data are updated and available. Please see PO_LAB_01 procedure and IO_LAB_02 instruction.	**Fulfilled**
8.2	The laboratory must use documented procedures and appropriate statistical techniques for the selection of samples, when the sampling is performed as part of the test.	Please see PO_LAB_01 procedure and IO_LAB_02 instruction.	**Fulfilled**
8.3	The laboratory must subject the calculations and data transfers to the appropriate reviews.	Please see PO_LAB_01 procedure.	**Fulfilled**
8.4	The laboratory must have procedures to the safety prevention of data from computational records.	Please see PO_24 procedure.	**Fulfilled**
9	**HANDLING OF ITEMS**		
9.1	The laboratory must identify in an unequivocal way the items to be tested, so as there is no mistake, at any time, as to their identification.	A permanent marker identifies unequivocally each testing sample.	**Fulfilled**
9.2	The laboratory must have documented procedures and appropriate facilities to avoid deterioration or damage to the test item during the storage, handling, and preparation of the test item.	Test items are stored internally and handled properly, in order to avoid any kind of deterioration. Please see planimetry DI_LAB_34 and §5.8 of quality book MQ17025 Rev.2	**Fulfilled**

10	**RECORDS**

10.1	The laboratory must maintain a record system suitable for particular circumstances, and must meet the applicable regulations, as well as the recording of all original observations, calculations, and resulting data, records and copies of test reports, for at least four years.	Testing records are stored in electronic format for at least 10 years. Please see §4.13 of quality book MQ17025 Rev.2 and RT_08 - Accredia requirements.	**Fulfilled**
10.2	The changes and/or mistakes in records must be stroke through, without removing or making the previous text illegible, and the new input must be clearly and unequivocally noted down by the side of the previous stroke through text, along the signature or initials of the person in charge.	Test records are controlled and signed twice by 2 different people.	**Fulfilled**
10.3	Records of test data must include at least: a) laboratory identification; b) sample identification; c) used equipment identification; d) relevant environmental conditions; e) measurement results and doubts, when appropriate; f) date and signature of the personnel who performed the task.	Records of test data meet the requirements. As example, please see test report RDL 371/14.	**Fulfilled**
10.4	All the records printed out by computers, calculators, charts and the like must be dated, initialed, and attached to the measurement records.	Records fulfill the requirements.	**Fulfilled**
10.5	All the records (technical and quality) must be maintained by the laboratory as to safety and confidentiality.	Testing records are stored in electronic format for at least 10 years. Please see §4.13 of quality book MQ17025 Rev.2. Confidentiality is assured by Non Disclosure Agreement declarations.	**Fulfilled**
11	**CERTIFICATES AND TEST REPORTS**		
11.1	The results from each test or series of tests conducted by the laboratory must be accurately, clearly, objectively, and unequivocally reported through a test report, and must include all the information required for the interpretation of test results, as required by the used method	Reports fully fulfill the requirements. As example, please see test report RDL 371/14.	**Fulfilled**
11.2	The laboratory must record all the information required to repeat the test, and such records must be available for the customer.	All test condition are recorded and reported in testing report. As example, please see test report RDL 371/14.	**Fulfilled**

11.3	Every test report must include at least the following information: a) title; b) laboratory name and address; c) report clinical identification; d) customer name and address; e) unequivocal description and identification of test item; f) characterization and condition of the test item; g) date the item was received and date of test conduction; h) reference to sampling procedures, when applicable; i) any deviations, additions or exclusions of test methods, and any other relevant information for a specific test, such as environmental conditions; j) measurements, review and originated results, supported by tables, charts, schemes and pictures; k) statement of the estimated uncertainty of test result (when applicable); l) signature, title or equivalent identification of personnel in charge of report content and issue date; m) when applicable, statement that the results refer only to test items; n) statement that the report must only be reproduced only in full and upon customer approval; o) item identification; p) reference to the specification of the used standard.	Reports fully fulfill the requirements. As example, please see test report RDL 371/14. For estimated uncertainty of test result, please see DI_LAB_12_02 procedure.	**Fulfilled**
12	**SUPPORT SERVICES AND EXTERNAL SUPPLIES**		
12.1	The laboratory must maintain records referring to the purchase of equipment, material and services, including: a) purchase specification; b) receipt inspection; c) calibration or review.	Responsability of quality and purchase departments. Please see DI_LAB_09 (suppliers list).	**Fulfilled**

ADDITIONAL NOTES:

MW ITALIA laboratory is getting ISO17025 accreditation.

All relevant docs named in this document are attached.

NONCONFORMITY REPORT	Requirement:	NCR: ____ / ____

1. Description:

Timing for corrective actions closing: 30 days

The closure of nonconformities will be done by:

☐ Submission of documents ☐ Re-audit on-site

The company must perform a root cause analysis with recording of appropriate actions as indicated below. Optionally, the actions can be recorded in the company's own format as long as it contains all the items mentioned below.

2. Containment Actions / Correction:

3. Root Cause Analysis:

4. Corrective Actions:

Responsible: Due Date:

5. Closure of Corrective Action (IQA use):

☐ Satisfactory ☐ Unsatisfactory

Responsible: Due Date:

The signatures in the table below are optional, where the auditor and client are aware and they agree with the information described in this document.

Auditor Name and Signature:	Francesco Spinazzola	Data: 13/01/2015
Client Name and Signature:	Luca Lorenzetti	