

EUROPEAN LEGAL FRAMEWORK FOR MOTOR VEHICLES AND THE NOVELTIES THAT EU REGULATION 2018/858 ON THE APPROVAL AND MARKET SURVEILLANCE OF MOTOR VEHICLES WILL INTRODUCE



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MOTOR VEHICLE REGULATION 2018/858

- became **fully applicable on 1st September** and replaced the Motor Vehicle Directive
- Regulation, but considered as one of the *“New Approach Directives”*
- The Regulation reformed the **type-approval and market surveillance system for motor vehicles in the EU**. This reform aims:
 1. to enable the **detection of non-compliance cases at an early stage** in the new system and minimize the differences in interpretation and application
 2. to modernise the current system and improvement of **control tests on car emissions**
 3. to achieve a high level of safety and **environmental performance** of vehicles

MAIN CHANGES:

- the **quality of testing** that allows a vehicle to be placed on the market through technical services
- **market surveillance** to control the conformity of vehicles that are already on the market,
- possibility of member states and the Commission to carry out **spot-checks on vehicles**
- the **oversight of the type-approval process**, the Commission to be able to carry out periodic assessments on national type-approval authorities and through the establishment of a Forum for the exchange of information on enforcement



SCOPE

- **motor vehicles of categories M and N and their trailers of category O**, that are intended to be used on **public roads**

- Category M – motor vehicles designed and constructed primarily for the carriage of passengers and their luggage
- Category N - motor vehicles designed and constructed primarily for the carriage of goods Three sub-categories have been identified
- Category O – trailers with a mass between 0,75 and 10 tonnes

- vehicles designed and constructed in one or more stages, systems, components and separate technical units, as well as parts and equipment, designed and constructed for such vehicles and their trailers

PATH TO EU MARKET

- All vehicles must comply with the requirements of the regulatory acts listed in Annex II

ANNEX II

REQUIREMENTS FOR THE PURPOSE OF EU TYPE-APPROVAL OF VEHICLES, SYSTEMS, COMPONENTS OR SEPARATE TECHNICAL UNITS

PART I

Regulatory acts for EU type-approval of vehicles produced in unlimited series

Item	Subject	Regulatory act reference	Applicability										STU or component
			M ₁	M ₂	M ₃	N ₁	N ₂	N ₃	O ₁	O ₂	O ₃	O ₄	
1A	Sound level	Regulation (EU) No 540/2014 of the European Parliament and of the Council (*)	X	X	X	X	X	X					X
2A	Emissions (Euro 5 and Euro 6) light duty vehicles/access to information	Regulation (EC) No 715/2007	X ⁽¹⁾	X ⁽¹⁾		X ⁽¹⁾	X ⁽¹⁾						X
3A	Prevention of fire risks (liquid fuel tanks)	Regulation (EC) No 661/2009 UN Regulation No 34	X	X	X	X	X	X	X	X	X	X	
3B	Rear underrun protective devices (RUPDs) and their installation; rear underrun protection (RUP)	Regulation (EC) No 661/2009 UN Regulation No 58	X	X	X	X	X	X	X	X	X	X	X
4A	Space for mounting and fixing rear registration plates	Regulation (EC) No 661/2009 Commission Regulation (EU) No 1003/2010 (**)	X	X	X	X	X	X	X	X	X	X	

EU TYPE-APPROVAL PROCESS:

1. Compilation of necessary documentation

- the manufacturer can choose one of the following procedures:

(a) **step-by-step** type-approval (b) **single-step** type-approval (c) **mixed** type-approval (d) **multi-stage** type-approval (incomplete or completed vehicle)

2. Submission to the EU authority

- the manufacturer has to submit an application for the EU type-approval with the information folder to the **approval authority**
- only one application, to only one Member State, to only one approval authority

3. Issuance of the EU type-approval certificate

4. Placing on the EU market

5. Post marketing activities

THE APPLICATION FOR EU TYPE-APPROVAL

- Application of each particular type of vehicle, system, component has to include a **Declaration of the manufacturer** certifying that:
 - (a) the manufacturer has **not applied for an EU type-approval for the same type to any other approval authority**, and no other approval authority granted the manufacturer such an approval;
 - (b) **no** approval authority has **refused** to grant type-approval of that type;
 - (c) **no** approval authority has **withdrawn** type-approval of that type;
 - (d) the manufacturer has **not revoked** an application for a type-approval of that type

- The **information folder** must be submitted in **electronic format** and include:
 - (a) **an information document**
 - (b) **all data, drawings, photographs and other relevant information;**
 - (c) for vehicles, **an indication of the procedure or procedures chosen;**
 - (d) **any additional information requested by the approval authority**

CONFORMITY ASSESSMENT

- for the purpose of granting EU type-approvals, the approval authority has to take the necessary measures in accordance with **Annex IV** to verify, if necessary in cooperation with the approval authorities of other Member States, that the manufacturer produces the vehicles in conformity with the approved type by means of appropriate tests that are performed by its technical service

L 151/186

EN

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ANNEX IV

CONFORMITY OF PRODUCTION PROCEDURES

- Notification of EU type-approval can be:

- Granted
- amended
- refused
- withdrawn

1. Objectives

- 1.1. The conformity of production procedure aims to ensure that each vehicle, system, component and technical separate unit, part or equipment produced is in conformity with the approved type.
- 1.2. The conformity of production procedure shall always include the assessment of quality-assurance management systems, referred to in point 2 as the 'initial assessment', and the verification of the type-approval subject and product-related controls, referred to in point 3 as 'product conformity arrangements'.

2. Initial assessment

- 2.1. Before granting type-approval, the approval authority shall verify that the manufacturer has established satisfactory arrangements and procedures for ensuring that vehicles, systems, components, separate technical units or parts and equipment are produced in conformity with the approved type.
- 2.2. Guidance for conducting those assessments may be found in standard EN ISO 19011:2011 — Guidelines for auditing management systems.
- 2.3. Compliance with the requirements of point 2.1 shall be verified to the satisfaction of the approval authority, as follows:

The approval authority shall be satisfied with the initial assessment and the product conformity arrangements referred to in point 3, taking into account one of the arrangements referred to in points 2.3.1 to 2.3.3, or a combination of those arrangements in full or in part as appropriate.

EU TYPE-APPROVAL CERTIFICATE



➤ The EU type-approval certificate has to contain the following attachments:

(a) the information package;

(b) the test reports (for a system, component or separate technical unit type-approval) or the test results sheet (for whole-vehicle type-approval);

(c) the name and the specimen of the signature of the person or persons authorised to sign the certificates of conformity and a statement of their position in the company (for whole-vehicle type-approval)

(d) filled-out specimen of the certificate of conformity of the vehicle type (for whole-vehicle type-approval)

CERTIFICATE of EU TYPE-APPROVAL No. DK 0199.195 revision 1 PS50-M NON-AUTOMATIC WEIGHING INSTRUMENT

Issued by DELTA Danish Electronics, Light & Acoustics
EU - Notified Body No. 0199
In accordance with the requirements for the non-automatic weighing instrument of
EC Council Directive 2009/23/EC.

Issued to Dibal S.A.
Asintze Kalea 24 (Pol.Industrial,Neiver)
48100 Derio (Vizcaya)
Spain

In respect of Non-automatic weighing instrument designated PS50-M with variants of
modules of load receptors, load cells and peripheral equipment.
Accuracy class III, single-interval or multi-interval (2 intervals)
Maximum capacity, Max: From 3 kg up to 25 kg
Verification scale interval; e = Max/ n
Maximum number of verification scale intervals; n ≤ 3000.
Variants of modules and conditions for the composition of the modules are set
out in the annex.

The conformity with the essential requirements in annex 1 of the Directive is met by the ap-
plication of the European Standard EN 45501:1992/AC:1993.

The principal characteristics and approval conditions are set out in the descriptive
annex to this certificate.

The annex comprises 8 pages.

Issued on 2010-11-04
Valid until 2019-10-07

Signature: J. Hovgard



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Danish Electronics,
Light & Acoustics

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2870 Hørsholm
Denmark

Tel: (+45) 72 59 40 00
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VAT No. DK 12275110

EU TYPE-EXAMINATION CERTIFICATE

Certificate No.: 18-PED-ROD-B-PT-18-20591133-01 Issue date: 2018-11-14 Valid from/until: 2018-11-13 - 2028-11-13
This certificate consists of 4 pages

This is to certify that representative examples of products manufactured by
Gritco Equipment B.V.
Klompemakersstraat 16d, 2984BB, Ridderkerk, The Netherlands

have been assessed with respect to the conformity assessment procedure described in
**ANNEX III MODULE B-PRODUCTION TYPE OF DIRECTIVE
2014/68/EU ON PRESSURE EQUIPMENT**

and found to comply with the requirements in Annex I – Essential Safety
Requirements of the Directive.

The certificate is valid for the following products:

Type of Pressure Equipment	Assembly
Product Name	Shot blast assemblies
Product Version	BM and MM series

Place and date:
Barendrecht, 2018-11-14

For EU-Conformity Assessment Body 2588:
DNV GL Business Assurance B.V.

Peter van der Wal
Responsible Design Approval Engineer

Chris van den Berg
DNV GL Representative

Lack of fulfillment of conditions as set out in the Certification Agreement may render this Certificate invalid.

SPECIAL SET OF OBLIGATIONS OF MANUFACTURER CONCERNING THEIR VEHICLES ARE NOT IN CONFORMITY OR THAT PRESENT A SERIOUS RISK – ART. 14

1. Where a vehicle, system, component, separate technical unit, part or equipment that has been placed on the market or that has entered into service is not in conformity with this Regulation or where the type-approval has been granted on the basis of incorrect data, the manufacturer shall immediately take the corrective measures necessary to bring that vehicle, system, component, separate technical unit, part or equipment into conformity, to withdraw it from the market or to recall it, as appropriate.

The manufacturer shall immediately inform the approval authority that granted the type-approval in detail of the non-conformity and of any measures taken.

2. Where the vehicle, system, component, separate technical unit, part or equipment presents a serious risk, the manufacturer shall immediately provide to the approval authorities and market surveillance authorities detailed information on the risk and on any measures taken in relation thereto.

3. Manufacturers shall keep the EU type-approval certificates and their attachments referred to in Article 28(1) for a period of 10 years after the end of validity of the EU type-approval of a vehicle and for a period of five years after the end of validity of the EU type-approval of a system, component or separate technical unit.

Manufacturers of a vehicle shall keep at the disposal of the approval authorities for a period of 10 years from the date of manufacture of the vehicle a copy of the certificates of conformity referred to in Article 36.

4. Manufacturers shall, following a reasoned request from a national authority or the Commission, provide that authority or the Commission, with a copy of the EU type-approval certificate, or the authorisation referred to in Article 55(1) demonstrating conformity of the vehicle, system, component, separate technical unit, part or equipment, in a language that can be easily understood by the national authority or the Commission.

Manufacturers shall, following a reasoned request from a national authority, cooperate with that authority on any action taken in accordance with Article 20 of Regulation (EC) No 765/2008 to eliminate the risks posed by the vehicle, system, component, separate technical unit, part or equipment that they have made available on the market.

ECONOMIC OPERATORS

1. European Representative

- (a) Has access to the EU type-approval and to the certificate of conformity
- (b) Provides all information, documentation and technical specifications, necessary to demonstrate the conformity to the approval authority
- (c) **Cooperates with the approval authorities** or market surveillance authorities on any action taken to eliminate the serious risk
- (d) **Informs the manufacturer about complaints and reports relating to risks, suspected incidents or non-compliance issues**



The Authorized Representative Name, Address and Contact detail should be written behind this logo.

This should be on the labeling material and can be on the marketing material

2. IMPORTER AND/OR DISTRIBUTOR

- ✓ Verify that the vehicle is covered by a valid EU type-approval certificate and that the system, component or separate technical unit bears the required type-approval mark and complies with all the technical requirements
- ✓ Has **access to the EU type-approval**
- ✓ indicate their name, registered trade name or registered trade mark, and their contact address on the vehicle
- ✓ ensure that the vehicle, system, component or separate technical unit is accompanied by instructions and information in the official languages of the Member States concerned
- ✓ **Keep record of complaints and recalls and communicate with distributors and manufacturer**



Special set of obligations of importer and distributor concerning their vehicles are not in conformity or that present a serious risk – art. 17 & art. 19

1. Where a vehicle, system, component, separate technical unit, part or equipment that has been placed on the market by importers is not in conformity with this Regulation, importers shall immediately take the corrective measures necessary to bring that vehicle, system, component, separate technical unit, part or equipment into conformity under the manufacturer's supervision, to withdraw it from the market or to recall it, as appropriate. Importers shall also inform the manufacturer and the approval authority that granted the EU type-approval.

2. Where a vehicle, system, component, separate technical unit, part or equipment that has been placed on the market presents a serious risk, importers shall immediately provide detailed information on the serious risk to the manufacturers and the approval authorities and market surveillance authorities.

Importers shall also inform the approval authorities and market surveillance authorities of any action taken and give details, in particular of the serious risk and of any measure taken by the manufacturer.

3. Importers shall, for a period of 10 years after the end of the validity of EU type-approval of a vehicle and for a period of five years after the end of the validity of the EU type-approval of a system, component or separate technical unit, keep a copy of the EU type-approval certificate and its attachments referred to in Article 28(1), and shall ensure that they can be made available to the approval authorities and market surveillance authorities upon request.

4. Importers shall, following a reasoned request from a national authority, provide that authority with all information and documentation necessary to demonstrate the conformity of a vehicle, system, component or separate technical unit, in a language that can be easily understood by that authority.

Importers shall, following a reasoned request from a national authority, cooperate with that authority on any action taken in accordance with Article 20 of Regulation (EC) No 765/2008 to eliminate the risks posed by the vehicle, system, component, separate technical unit, part or equipment that they have made available on the market.

2 CASES WHERE THE OBLIGATIONS OF MANUFACTURERS APPLY TO IMPORTERS AND DISTRIBUTORS

1. When the importer or distributor makes available on the market, or is responsible for the entry into service of a vehicle under its own name or trademark, or modifies a vehicle in such a way that it may no longer comply with the applicable requirements



2. When the importer or distributor makes available on the market or is responsible for the entry into service of a system, component or separate technical unit on the basis of a UN type-approval that was granted to a manufacturer outside of the EU, and it is not possible to identify manufacturer's EU representative

POST MARKET SURVEILLANCE

The EC and all Member States must use the common electronic exchange systems:

1. **Rapid Information System (RAPEX)**
2. **the Information and Communication System on Market Surveillance (ICSMS) for EU type-approval certificates, test reports, amendments, refusals or withdrawals of EU type-approval**



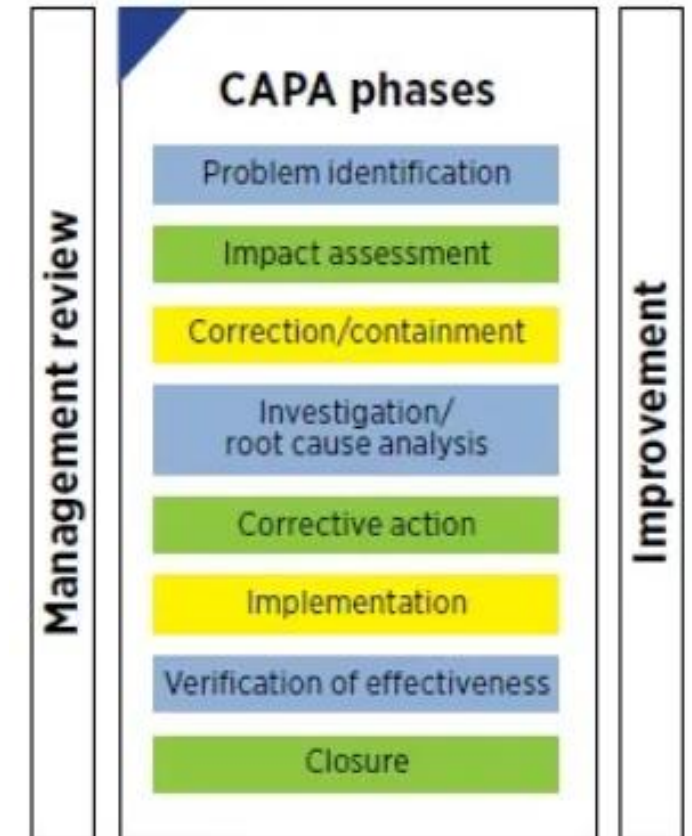
➤ Any complaint relating to risks, suspected incidents or non-compliance must be examined by manufacturer

- If the manufacturer has placed a product on the market that is **not in conformity** or where the type-approval has been granted on the basis of incorrect data, the manufacturer has to take the **corrective measures** and inform the approval authority about it.
- Where the vehicle, system, component, separate technical unit, part or equipment presents a **serious risk**, the manufacturer has to provide to the authorities **detailed information on the risk** and **on any measures he had taken**.

FIGURE 1

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The 8 phases of the CAPA process



CAPA = corrective and preventive action

GENERAL SAFETY REGULATION 2019/2144 ON TYPE-APPROVAL

- *Regulation 2019/2144 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users*
- Entered into force 5th January this year
- **All vehicle models introduced on the EU market to be equipped with advanced safety features, as of July 2022:**
 - Advanced emergency braking, Alcohol interlock installation facilitation, Drowsiness and attention detection, Distraction recognition / prevention, Event/accident data recorder, Emergency stop signal, Full-width frontal occupant protection crash test - improved seatbelts, Head impact zone enlargement for pedestrians and cyclists -safety glass in case of a crash, Intelligent speed assistance, Lane-keeping assist, Pole side impact occupant protection, Reversing camera or detection system, Tyre pressure monitoring system, Vulnerable road user detection and warning on front and side of the vehicle, Vulnerable road user improved direct vision from the driver's position*

➤ The objective of the Regulation is to:

1. Assure the **safety of vehicles**, vehicle occupants and vulnerable road users;
2. Improve fuel efficiency, **CO2 emissions** and generally environmental impact;
3. Increase **mobility** and improve the E competitiveness on the global market



REGULATION 2018/858 & REGULATION 2019/2144

- OTA software update of motor vehicles
 1. *Compliance & proper assessment of the Notified Bodies*
 2. *Cybersecurity – are our vehicles exposed to hackers?*
 3. *International harmonization*
 4. *Data collection and privacy concerns*



- Over-The-Air (OTA) update is the delivery of new software or data through wireless technology
- Other New Approach Directives -> Smartphones -> Radio Equipment Directive ->EC recently issued Clarifications on the initiative of upload of software into radio equipment

1. Can OTA software update lead to non-conformity?

- Compliance is demonstrated the moment of placing the vehicle on the market

2. How can the Notified Bodies properly assess the compliance and assure that the vehicle can remain compliant, especially after the software has been uploaded?

- Cybersecurity issues concerning the capability to change the vehicle's behaviour or to reprogram it, if a new software is uploaded
- In 2015, researchers exposed vulnerabilities in [Jeep's Cherokee](#) by hacking into the car by turning the windshield wipers on and suddenly braking the car from a 10 miles distance

3. Global regulatory set-up

- In the EU - Homologation based on type-approval and WVTA
- In the USA and Canada - the OEM certifies that the vehicle complies with all rules, such as FMVSS in the USA and CMVSS in Canada + other voluntary agreements such as NCAPs. OEMs must have documentation and all tests available in case the authorities come
- In 2019, Sweden threatened to ban [Tesla](#) sales because of the unclear OTA update and Autopilot concerns
- International harmonization (UNECE's draft for the new UN Regulation on uniform provisions concerning the approval of software update processes)

4. Compliance with GDPR

IS THIS →
COMPLIANT WITH
EU
REGULATIONS?



Elon Musk @elonmusk · 20. kol

New Tesla feature coming that enables your car to play snake jazz or Polynesian elevator music through its outside speakers wherever you go

48 tis.

11,5 tis.

147,6 tis.



Elon Musk prosljedio/la je Tweet



Tesla @Tesla · 19. kol

Big updates in 🇨🇦

- Trans-Canada Supercharging ✓
- Model Y deliveries ✓
- Leasing for Model Y & Model 3 🔍



How attractive is the EU for manufacturers?

THANK YOU!!!

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