

POSITION PAPER

VDMA recommendations for the Digital Omnibus

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1. Introduction: The time to act on simplification is now

The EU's Competitiveness Compass has identified the simplification of the regulatory environment as one of the horizontal enablers to improve competitiveness across all sectors. We fully share this view, as our companies increasingly perceive EU-Regulation as a burden which is threatening their innovation capabilities and competitiveness.

The European machinery and equipment manufacturers feel the regulatory burden even more than other sectors, as they must comply with many technology-specific and sectorial pieces of legislation and, as an export-oriented sector, compete with companies in other regions that have a lighter regulatory burden. In addition, the sector is dominated by SMEs or midcaps that innovate in small series and cannot spread compliance costs over large series and don't have large resources to handle regulatory issues.

As a digitalization of industry advances, almost all machinery provided by our sector is digitalized, connected and innovation is increasingly driven by digital technologies. Machinery and Manufacturing equipment is fully in scope of the EU's acquis for digital regulation, which is, together with other regulatory areas, increasingly becoming a burden for innovation and competitiveness, outweighing the benefits in terms of legal certainty and harmonization.

Therefore, VDMA welcomes the European Commission's plan to simplify digital regulations with a "Digital Omnibus". Improving digital regulations is needed to relieve the burden and to unleash a wave of innovation which is necessary for productivity and competitiveness – not only in the machinery industry, but also in our customer sectors.

The opportunity must not be missed, and we call upon the EU institutions to launch the Digital Omnibus as a bold and comprehensive initiative which must not shy away from covering recent dossiers such as the AI Act, the Data Act and the CRA. Chapter 3 contains concrete and detailed recommendations for improvements for these three, but also for the GDPR and NIS 2.

2. General principles for an effective Digital Omnibus

VDMA is convinced that a substantial simplification is possible without sacrificing protection of values or ambition for Single Market harmonization, if the right regulatory concepts are applied and better regulations principles are observed. More precisely, the digital omnibus is needed as

a prerequisite for a digital single market. Therefore, we propose to make the following principles the reference to ensuring an ambitious and efficient digital omnibus:

- **New Legislative Framework for product regulation¹:**
The core legal documents should be limited to clear general principles, with essential requirements set out in the regulation and the definition of the state of the art and its implementation left to standardization. Together with the concept of the “conformity assessment by the manufacturer”, these principles of the New Legislative Framework (NLF) ensure that legislation is technology-neutral, future-proof and flexible to take account of technological innovation and new developments.
- **The competitiveness check of existing digital regulation must be the basis, examining if the regulation is a competitive disadvantage for EU-companies in global markets**
The impact on global competitiveness must be assessed, for example, by including critical benchmarking with governance in other regions. If EU regulation differs from that of other countries, this should not be seen as a competitive advantage or a ‘best practice’ to be followed by others. Instead, divergences should be a reason to examine their impact on the EU’s competitiveness, considering harmonization initiatives and an n of the EU’s approaches.
- **Reality checks must verify if the required measurements are feasible and the data are available**
No provisions must be maintained if it is not clear how target parameters can be measured. Without this precondition, massive uncertainties will hamper implementation and distort a fair application of the rules.
- **The use of secondary regulation such as Delegated acts must be limited**
The European Commission has committed to reducing administrative burdens in the EU by at least 25%, and by at least 35% for SMEs. This reduction target could be operationalized as a mandate to Commission services, including desk officers and Standing Committees, to identify and remove redundant or disproportionate provisions in current product legislation. The number of secondary legislations is around ten times higher than the number of regulations and directives. Therefore, without a significant contribution from a reduction in delegate acts, the Commission will probably not reach its own ambitious goal.
- **Remove overlaps and inconsistencies through a “one law only”-clause:**
In many cases, similar risks and objectives are addressed in different pieces of legislation, leading to duplication of compliance burdens or even inconsistencies.

¹ VDMA Position Paper: <https://vdma.eu/viewer/-/v2article/render/147663847>

Where such overlaps do not cover actual regulatory gaps, a simple clause could clarify which provisions take precedence.

- **Avoid or explain deviations from established general legal principles:**

We believe that the process of making laws would be made significantly more efficient in producing good regulations, if it consistently had to explain why a deviation from established legal principles was introduced.

3. Concrete Recommendations on Legal Acts

For the machinery industry, the AI Act, the Data Act, the GDPR and the CRA have created substantial uncertainties and burdens. It's a must that Digital Omnibus covers these legal acts. In addition, it must also be scrutinized if there are misalignments or inconsistencies with non-digital regulation (e.g. impact of digital regulation on ESPR) or if non-digital dossiers contain burdensome digital requirements (e.g. reporting or notification).

3.1 AI Act

Context:

The implementation of the AI Act poses major challenges for companies and authorities. One of the reasons is the “high-risk” classification, which is still fraught with considerable ambiguity and leads to legal uncertainties. Among other things, the interaction between the legal acts listed in Annex 1 (e.g. Machinery Regulation (EU) 2023/1230) and the AI Act leads to uncertainties for companies and double regulation of products.

Proposal:

In the interests of coherent, proportionate and user-friendly regulation, VDMA calls for the deletion of Article 6(1) and Annex I (1) of the AI Act.

Justification:

These provisions lead to an automatic high-risk classification of AI systems that are considered safety components in accordance with the Machinery Regulation (EU) 2023/1230. Such a blanket classification contradicts the aim of simplification and creates disproportionate complexity and uncertainty for manufacturers.

The Machinery Regulation 2023/1230 already contains a proven and differentiated system for risk assessment and conformity assessment of safety-relevant components. This not only comprises more than half of the text of the regulation but is also supplemented by over 1000 harmonized standards that currently have “safety” in their title.

The key aspect here is that the Machinery Regulation (EU) 2023/1230 itself already contains regulations on the integration of AI components and fully covers AI-related risks. It explicitly refers to software and machine learning solutions in safety components and obliges manufacturers to carry out a third-party risk assessment of these technologies in the context of the overall machine.

An additional, blanket high-risk classification under the AI Regulation therefore constitutes double regulation. **It will also foreseeably lead to safety-enhancing AI- components not being installed because the duplicate regulatory requirements discourage development - even though AI offers enormous potential for increasing safety on the shop floor.** In addition, the current interplay between the AI-Act and vertical regulations as it is currently laid down in the AI-Act creates confusion and legal uncertainty which goes beyond the regulation of AI in safety components.

3.2 Data Act

Context:

The Data Act does not meet the needs of the industry and has created a high level of legal uncertainty and bureaucracy for industrial companies. The nature and complexity of industrial data processing procedures, particularly in the manufacturing industry, must be adequately taken into account if competitiveness of European companies is to be increased by data sharing. In addition to the more general suggestions above, the following specific points need to be addressed:

Proposal:

Addition to Article 1 paragraph 4 Data Act: „*Where this Regulation refers to connected products or related services, such references are understood to include virtual assistants for consumers insofar as they interact with a connected product or related service.*“

Justification:

Article 1 paragraph 4 Data Act should solely focus on consumer constellations. The restriction to consumers would bring organizational simplifications for companies, especially in the B2B sector. It would also promote the development of virtual assistants if companies had the opportunity to use them in the B2B sector first.

Proposal:

Revision of the definition of the term “data holder”, Article 2 paragraph 13 Data Act.

Justification:

The definition of “data holder” is unclear and circular. According to the wording of the Data Act, the data holder could also be the user of a connected product or related service (especially in complex scenarios), although it has already been clarified that users and data holders cannot be the same person or company in relation to the same product or service. In its FAQ on the Data Act, the EU-Commission itself also deviates from the wording of the legal definition and only focuses on who controls access to the readily available product data and related service data and no longer addresses the requirement stemming from the legal definition that only those who provide a related service and retrieve or generate data during the provision of this related service can be data holders. This incongruence leads to uncertainties in assessing when a company is actually in the role of the data holder and makes the implementation of the Regulation considerably more difficult due to this legal uncertainty.

Proposal:

Deletion of Article 4 paragraph 12 Data Act.

Justification:

The Regulation itself should constitute the legal basis for the sharing of personal data. The way Article 4 paragraph 12 Data Act is currently worded leads to considerable uncertainties and organizational efforts in data protection for companies. To fulfil their obligation of sharing data under the Data Act companies are currently not allowed to rely on the initial legal basis for the collection of personal data; instead, they have to decide on a case-by-case basis on which legal basis under the GDPR the personal data may or may not be disclosed, which in practice leads to considerable additional effort. This hinders both the effective implementation of data protection and the Data Act.

Proposal:

Adaption of Article 5 paragraph 1 Data Act: „(1) ***To the extent that the user cannot access the data directly from the connected product or related service, upon request by a user or by a party acting on behalf of a user, the data holder shall make readily available data and the relevant metadata necessary to interpret and use those data to a third party without undue delay, [...]***“

Justification:

To avoid ambiguity, Article 5 paragraph 1 Data Act should be limited to the same case of application as Article 4 paragraph 1 Data Act.

Proposal:

Extension of Article 7 paragraph 1 Data Act to medium-sized enterprises and small mid caps.

Justification:

With the Omnibus Package IV, the EU-Commission wants to introduce a new category of companies, so-called small mid-caps, to which certain SME exemptions are to apply that previously only applied to micro and small companies. In line with the new EU Commission's declared aim of reducing bureaucracy Article 7 paragraph 1 sentence 1 Data Act should also apply to medium-sized companies and small mid-caps. Those are the engine of the German and European industry and drivers of innovation and should not be restricted in the development of new innovations by excessive regulation. Consequently, in the event of an extension to medium-sized companies and small mid-caps, Article 7 paragraph 1 sentence 2 Data Act should be deleted.

Proposal:

Deletion of Article 13 paragraph 4 and paragraph 5 Data Act

Justification:

What is considered unfair is generally determined by the applicable law of the Member State in which the contract is concluded. Article 13 paragraph 4 and paragraph 5 Data Act are redundant. Article 13 paragraph 4 and paragraph 5 Data Act go far beyond what is necessary and severely restrict the freedom of contract between companies. Alternatively, the words "in particular" in Article 13 paragraph 4 first sentence of the Data Act should at least be deleted in order to create a little more legal clarity.

Proposal:

Suspend applicability of the Data Act for used products placed on the market before 12 September 2025

Justification:

The Data Act does not clarify whether used products, placed on the market before 12 September 2025, which are now being resold, are subject to the Data Act or not. According to Article 50 Data Act, such products are not subject to the design obligation resulting from Article 3 Data Act, however the applicability of other obligations is not expressly excluded. Anyone who resells used connected products that were already placed on the market before the effective date must currently fear that they will be subject to the extensive obligations of the Data Act — for example, the information obligations under Article 3 paragraph 2 Data Act — in the same way as a manufacturer or distributor who places a connected product on the market for the first time. Anyone wishing to sell a used connected product that is several years old will be confronted with unpredictable additional obligations and the associated bureaucracy. Such information about the connected product may no longer be available, as it was when it was first purchased. The seller would therefore first have to contact the manufacturer to ask them to kindly provide the relevant information. It is questionable whether the manufacturer is even able to do this

(anymore). This could significantly restrict the resale of used connected products. The resulting consequences for the secondary market cannot be desirable from an economic, competitive, or sustainability perspective. It must therefore be clarified that the Data Act does not apply to connected products that were placed on the market before 12 September 2025.

3.3 GDPR

Context:

The GDPR has a uniform data protection approach. The Regulation doesn't differentiate between data processing activities but rather sets the same prerequisites for any processing of personal data, irrelevant of the risk for the data subject affected. This approach is appropriate for companies which business models rely on the processing of large volumes of personal data. In such cases data privacy should be thought and practiced in a comprehensive way to ensure that natural persons and their personal data are protected. However, when it comes to situations where personal data is merely a byproduct and isn't processed any further, there should be exemptions from certain provisions of the GDPR, which impose a huge organisational burden on companies, especially small and medium enterprises.

Proposal:

Implementation of a risk-based approach: The GDPR should differentiate between processing activities based on the risk they pose to the rights of the data subjects.

Justification:

Where the processing of personal data means no to little risk for the data subject, there is no need for the same protection measures as the processing of personal data that poses high risks to the rights of data subjects requires. For example, where the processing of personal data is a mere byproduct, e.g. when a staff number of a natural person is stored on a machine, which is operated by that person, and that number isn't processed any further, the risk could be considered little, if not non-existent. In that case, there is no need for extensive information obligations or a record of processing activities to protect such personal data. For small and medium enterprises, a risk-based approach would mean a more manageable and consequently more efficient implementation of data protection mechanisms and therefore ultimately lead to wider acceptance of data privacy legislation. It would reduce the risk of data privacy being seen as a burden more often than as a prerequisite for secure data processing.

Proposal:

Harmonization of national data protection legislation throughout the European Union.

Justification:

Each Member State has its own GDPR implementation acts which in certain cases might be necessary, but which also lead to national regulations going beyond the level of protection of the GDPR. National legislation should be harmonized. There are certain opening clauses in the GDPR, which are necessary, however, that should not lead to different levels of data protection throughout the European Union. It should be ensured that the national implementation doesn't go beyond what is considered necessary on an EU level.

3.4 Cyber Resilience Act

Applicability of Article 14 to products placed on the market in the past**Context:**

In the current version of the CRA, Article 69(3) provides for the application of Article 14 to existing products that were placed on the market in the past (before 11 December 2027). This creates significant uncertainty for companies regarding products that were placed on the market, in some cases, decades ago. (For the current Article 69(3) wording and dates, see the OJ text.)

Proposal:

Deletion of Article 69(3).

Correction of Art. 71. (2):

2. This Regulation shall apply from 11 December 2027.

However, Chapter IV (Articles 35 to 51) shall apply from 11 June 2026.

Justification:

In its current wording

"[...] the obligations laid down in Article 14 shall apply to all products with digital elements that fall within the scope of this Regulation that have been placed on the market before 11 December 2027"

this constitutes retroactive legislation, since Article 14 CRA would also have to be applied to products whose sale and development were completed before the CRA was even envisaged. In addition, for many physical products subject to CE-marking rules, there is an obligation to retain the technical documentation for a maximum of 10 years.

For many non-physical products, such as software, there are no regulations under current CE regulations according to the current legal situation. These products therefore have no technical documentation whatsoever.

It therefore cannot be guaranteed that manufacturers will be able to fulfil the reporting obligations under Article 14 for products placed on the market before 11. December 2027.

(Article 14 “Reporting obligations of manufacturers” and Article 69 “Transitional provisions” per OJ.)

Limiting the applicability of Article 14

Context:

In the current version of the CRA, the reporting obligations under Article 14 apply indefinitely and are not subject to any temporal limitation. This creates significant planning uncertainties for companies, since an unlimited temporal application of regulatory obligations cannot be meaningfully factored into any economic development process.

Proposal:

Extension of Article 14:

“The reporting obligations of manufacturers under Article 14 shall be limited to the duration of the support period of the product with digital elements.”

Justification:

An unlimited application of statutory provisions leads to permanent burdens, planning uncertainty and competitive disadvantages for manufacturers.

1. Legal and economic uncertainty

If a provision provides no foreseeable temporal end or review, it remains unclear—despite ongoing costs—whether this provision will continue to be sensible, proportionate or necessary in the future. Manufacturers must permanently anticipate obligations, even if the market, technology or risks have long since changed.

2. High and long-term costs

Permanent requirements lead to high fixed costs for, e.g., regular audits, documentation obligations, etc. Even when new technologies become established, old obligations remain in place and cause unnecessary expenditure.

3. Competitive disadvantages

In global markets, manufacturers may fall behind foreign competitors if those competitors are subject to more flexible rules. Moreover, the obligations under Article 14 could potentially be circumvented by spin-offs, which could likewise create a competitive disadvantage for manufacturers.

Start of application

Context:

The current start date for application of the CRA on December 11, 2027 applies to all products with digital elements along the entire supply chain. This means that the CRA must be fulfilled on the same day for everything from microchips and software to components, machines, and whole

production lines. In practice, this poses almost unsolvable problems, especially for manufacturers at the end of the supply and value chain.

For example, machine and plant manufacturers face the challenge of long cycle, verification, and validation times during development. Additional problems arise during the actual provision of the machine or plant due to the long lead times for the procurement of components.

Regardless of the CRA, this often leads to project durations of more than three years for many products of VDMA member companies, from planning to delivery.

The following factors further complicate implementation:

- Terms are sometimes inconsistent or unclear
- Harmonized standards are not available for all Products with Digital Elements
- Type examinations are only possible three months before the start of application
- Market surveillance for non-European manufacturers is insufficient

All these issues must be considered when the CRA comes into application.

Proposal:

In the course of the omnibus procedure for the CRA, the CRA should be revised to address the following issues so that all manufacturers and participants in the value chain have sufficient time and a clear legal framework to implement the legislation.

For successful implementation, standards must be available in good time, be internationally compatible, be based largely on international standards, and be applicable in practice not only to new developments but also to existing products.

The VDMA therefore calls for an appropriate phasing of the start of application, e.g., considering supply chain issues.

Uniform definitions

Context:

Some terms and definitions in the CRA are not consistent. Different formulations, such as “core function” and “core functionality,” are used inconsistently in the legal text, are difficult for users to understand, and make it difficult to interpret and apply the legal text consistently.

Justification:

Definitions and provisions should be harmonised and simplified across the different legal acts. In addition, any deviation from previously established definitions and provisions should be explained in the recitals.

Availability of product-specific harmonized standards beyond Annexes 3 and 4

Context:

Under the current standardization mandate, product-specific standards are only mandated for the core functions of Annex 3 Class 1 and 2 and Annex 4. In addition, horizontal standards are mandated, but these are not to be listed in the OJ. Because they are not to be listed, the presumption of conformity does not apply to these standards.

On the one hand, this leads to legal uncertainty for manufacturers and, on the other hand, to a third-party obligation for products that have several functions from Annexes 3 and 4.

Proposal:

Provide support to develop broad vertical standards that cover a wide range of products and functions (broad verticals) with a Presumption of Conformity.

Establishment of a further product category: Benign products

Context:

The scope of the CRA will include also trivial products with digital elements like simple sensors, passive electronic components, or basic switching devices (e.g. analog-to-digital converter, electric toothbrushes barcode readers). Even though the CRA will not require any additional cybersecurity protection measures due to the virtually non-existent cybersecurity risks, these products with digital elements will still have to go through the NLF formal conformity assessment to demonstrate CRA compliance with all processes, documents, and labelling requirements. Consequently, without any lower limits for such "benign products," costs are generated that have no discernible benefit for the manufacturer, the customer or society.

Proposal:

To address this imbalance, we propose introducing a specific exemption for "inherently benign products" under the CRA. This category would apply to products with digital elements that, due to their technical simplicity, cannot pose a cybersecurity risk. A precedent for such an approach exists in Recital 12 of the EMC Directive (2014/30/EU), which refers to products "inherently benign in terms of electromagnetic compatibility." A similar reference – "inherently benign in terms of cybersecurity" – would be appropriate and beneficial in the context of the CRA. To ensure legal certainty and prevent circumvention of the regulation, we propose the following definition:

Article 3 (5a): "benign product" means a product which cannot reasonably be expected to cause a cybersecurity risk because it is technically too limited to do so."

Simplification of documentation requirements

Context:

Technical documentation obligations for manufacturers are not proportionate for products which are not listed as important or critical products.

Proposal:

Extend the option of using a simplified format (as for SMEs under Article 33(5)) for fulfilling technical documentation obligations in the case of products which are not listed as important or critical products with digital elements.

Exemption for marine equipment under Article 2(4)**Context:**

The current version of the CRA provides an exemption for equipment falling within the scope of the Marine Equipment Directive 2014/90/EU. However, the scope of Directive 2014/90/EU is limited to a closed list in Commission Implementing Regulation (EU) 2025/1533. As a result, the sectoral exemption in Article 2(4) CRA is not applicable to a wide range of marine equipment, such as ship propulsion systems and engines, because these are not listed in the Annex to Implementing Regulation (EU) 2025/1533. In our view, this interpretation leads to a substantively inconsistent outcome, since many maritime products are already subject to a highly regulated environment—comparable to the automotive, medical devices or aviation sectors—and comply with the requirements of the IMO (International Maritime Organization) and the IACS (International Association of Classification Societies). We therefore take the view that the current drafting of the sectoral exemption for marine equipment in the CRA is incomplete and, in its current form, does not fully reflect the legislature's intention. This results in an objectively unjustified burden on maritime propulsion systems, which are already subject to their own international regulatory framework. (For the current CRA wording of Article 2(4), see: "This Regulation does not apply to equipment that falls within the scope of Directive 2014/90/EU...".)

Proposal:

Correction of Article 2(4):

"This Regulation does not apply to equipment that falls within the scope of Directive 2014/90/EU of the European Parliament and of the Council, or that is intended for use in the maritime domain and is subject to the requirements of the international maritime conventions SOLAS, MARPOL or COLREG, or is regulated by the International Maritime Organization (IMO) or the International Association of Classification Societies (IACS)."

Additional correction of Article 2(4) by adding the following recital:

"(XX) The sectoral exemption pursuant to Article 2(4) of this Regulation relates to equipment falling under Directive 2014/90/EU (Marine Equipment Directive). This exemption takes into account that marine equipment is already subject to a separate and comprehensive international regulatory framework, shaped in particular by conventions such as SOLAS, MARPOL and COLREG, and by organisations such as the International Maritime Organization (IMO) and the International Association of Classification Societies (IACS). In addition, specific

cybersecurity requirements already exist for certain product groups in the maritime sector, such as those laid down in IMO Resolution MSC.428(98) on the integration of cyber risk management into the ISM Code, as well as in the IACS Unified Requirements UR E26 ('Cyber Resilience of Ships') and UR E27 ('Cyber Resilience of On-Board Systems and Equipment'). Those requirements are binding for newly built ships as from July 2024 and ensure that maritime systems are subject to an equivalent level of technical, safety-related and cybersecurity-related regulation."

3.5 NIS2 Directive

Context:

With the national implementations of the Directive, some technical errors in the regulatory text have come to light, namely in the determination of the categories of facilities that should be changed, notably in the field of energy production and in the selection under REACH. Overall, there is a great deal of uncertainty for companies when determining as an important or essential entity.

In addition, the nationally designed reporting obligations lead to a high bureaucratic burden in the event of security incidents due to multiple parallel reporting obligations in different jurisdictions, which should be streamlined to an EU-wide single reporting leveraging a SPOR (Single Point of Reporting), either on national or EU level.

Proposal:

Addition of a provision as an essential business activity for the equipment category Energy Producers Annex I No. 1a: "*Producers as defined in Article 2, point (38), of Directive (EU) 2019/944 **if these activities are the main commercial or professional activity***"

Justification:

Companies that feed energy into the power grid with solar panels on the office building roof are generally within the scope of application as energy producers. This is a technical error in the Directive, as this category of entity initially only addresses energy generation companies whose main activity is attributable to the energy sector. It is to be feared that companies will otherwise do without a solar system, which cannot be in the interest of the legislator and the environment.

Proposal:

Change of the definition as an important entity in the chemical sector to include importers and exclude articles: "***Manufacturers and importers as referred to in Article 3, points 9 and 11 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of substances and mixtures as defined in Article 3 points 1 and 2 of aforementioned Regulation.***"

Justification:

The text of the Directive under ANNEX II No. 3 of the NIS2 Directive does not provide for a restriction regarding “articles” in the context of the REACH Regulation. This means that a yet undetermined number of European manufacturers are covered by this point, since manufacturing of articles means manufacturing of “any man-made object”. In principle, all manufacturers of substances, mixtures and articles are subject to ANNEX II No. 3 of the NIS2 Directive, unless they are exempted from application as micro and small enterprises due to the size of their company.

Additionally, while manufacturers are included, imports of chemicals are not included. This is a regulatory gap and should be addressed in the Directive.

Proposal:

Add in the reporting requirements in Article 23 of the NIS2 Directive the ability for essential and important entities to report significant incidents to the designated provider of the EU Single Reporting Platform (ENISA) as an additional option to fulfil all national reporting obligations. ENISA or the provider of the SRP shall forward reports without delay to the national CSIRTs.

Justification:

National reporting obligations vary from “anonymous online webform” to “national PKI-based authenticated forms on a distinct platform”. For multinational companies determined as important entities are obliged to report an cross-border event multiple times within 24h and in the language of the national authority. This is a significant burden for entities affected and leads to higher costs. The NIS2 Directive was designed to streamline cybersecurity across Europe and not to fragment it again. Providing an opportunity to report an incident once lowers the burden while maintaining the designated level of security intended.

Contacts:**Kai Peters**

Deputy Directory VDMA European Office
+ 32 7068219
E-Mail: kai.peters@vdma.eu

Kai Kalusa

Expert Digital Policy
+ 49 30 3069 4624
E-Mail: kai.kalusa@vdma.eu

Lobby Register: R000802

EU Transparency Register ID: 9765362691-45

[vdma.eu](https://www.vdma.eu)