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Support for the new batteries regulatory framework – DRAFT

Technical input for the Guidelines on removability and replaceability of portable and Light Means of Transport batteries

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1 Introduction

Article 11 of regulation (EU) 2023/1542, specifies in its paragraph 9 that the Commission shall publish guidelines to facilitate the harmonised application of the Article. This JRC report aims at providing technical input to the process for the development of Guidelines. The Guidelines themselves are expected to be subsequently published by Commission services in a separate document.

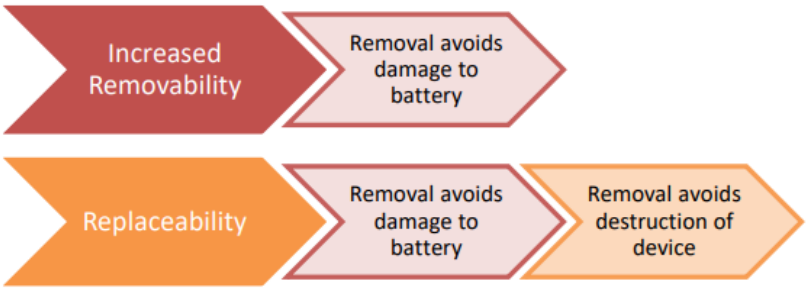
Drawing from existing literature of product policy and battery-powered devices, the JRC report provides technical insights into the aspects of removability and replaceability, and explores technical elements of the concepts of “independent professionals” and “compatible battery”, towards facilitating a harmonised understanding of the terms, and with the view to enabling that battery removal and replacement are conducted in a safe manner. The report also offers proposals for the qualification of the limited and full derogations foreseen in Article 11 of the regulation, by pointing to existing and established classification systems from other pieces of Union law or international standards.

2 Definitions and Article 11 general considerations

According to European Commission et al (2021), removability of the battery is understood to be possible when the battery can be safely taken out of a device (with or without the use of tools), avoiding damage to the battery, though in some cases resulting in the destruction of the device.

In turn, replaceability is defined as a battery (or battery pack) being "removable with tools commonly available to the end-user" and without destruction of the device or battery, thus enabling replacement to support further operation of the device. Figure 1 below demonstrates the difference between relevant concepts.

Figure 1. Hierarchy of removability, replaceability and interoperability and inclusion of other areas

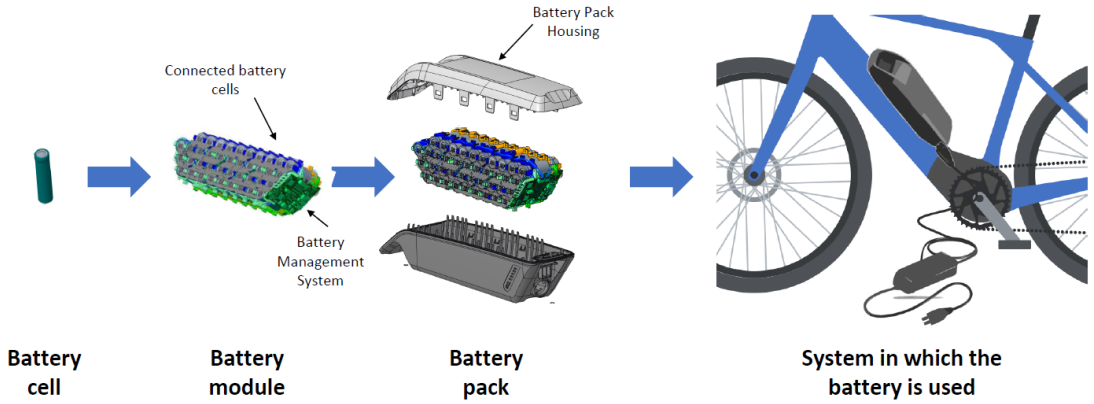


Source: Own adaptation from European Commission et al (2021)

This document aims at only qualifying the provisions in Article 11 of the regulation; not amend or expand them. Notably:

- The document applies to entire batteries or battery packs, and not to individual cells or other parts included in the batteries, except from the case of light means of transport (LMT) batteries as described in Art 11 (see Figure 2).
- The document only applies to batteries and products placed on the market once Article 11 come into force.
- Additionally, provisions related to removability and replaceability by an end-user, the end-user is assumed to be an adult.

Figure 2 Schematic representation of different levels of a battery system



Source: RECHARGE, 2023

The concept of compatible battery is referenced in paragraph 6, which specifies that: *"For the purposes of paragraphs 1 and 5, a portable battery or LMT battery shall be considered readily replaceable where, after its removal from an appliance or light means of transport, it can be substituted by another compatible battery without affecting the functioning, the performance or the safety of that appliance or light means of transport."*

Compatible battery is understood to be one that does not pose a risk for the user or the device safety, while allowing the device to operate seamlessly. The same consideration is understood for batteries consisting of multiple cells: a compatible cell is understood to be one that that does not render the battery pack unsafe, ideally having the same capacities, design and chemistry characteristics. For products which are subject to type-approval under regulation (EU) No 168/2013, a key component can be considered "compatible" only if its replacement has no impact on its type-approval specifications.

3 Paragraph 1 Qualifications

3.1 Removability and Replaceability parameters

In order to qualify battery removability and replaceability, the following parameters are provided. It has to be noted that the parameters refer to the whole disassembly process for the removal or replacement of the battery, not just to components directly in contact with the battery.

Tools

Guidance on tool types can be drawn from EN 45554:2020, which distinguishes between repairs without any need for tools, those that can take place with basic tools, product-group specific tools, other commercially available tools, proprietary tools, and repair not feasible with any tools.

Therefore, for the purposes of the implementation of Article 11, the following specifications can be proposed:

- → Regarding removability by end-users, the concept of removability refers to the use of commercially available tools, without requiring the use of specialized tools (unless provided free of charge with the product), proprietary tools, thermal energy, or solvents to disassemble.
- → Regarding removability by independent professionals, the concept of removability refers to the use of commercially available tools, without requiring the use of proprietary tools. As per EN 45554:2020, proprietary tools refer to tools not available for purchase by the general public or for which any applicable patents are not available to license under fair, reasonable, and non-discriminatory terms.

This means using fasteners and joining techniques that are compatible with the qualifications above. As such, permanent fixing such as using glue or welding is avoided, especially for end-user removability. The use of the same type of fasteners also improves removability, by reducing disassembly time and disassembly effort.

Disassembly Information

Paragraph 1 of Article 11 includes requirements on the availability of instructions and safety information on the use, removal and replacement of batteries. The following types of information are considered as relevant:

- a disassembly map or exploded view for the battery disassembly, reassembly and normal operation;
- technical manual of instructions for removal;
- software tools, firmware and similar auxiliary means required for full functionality of the device after battery replacement;
- relevant information to ensure a safe disassembly process, including conducting quality replacement process testing.

In all cases, battery removal and replacement should be performed according to the safety information on the use, removal and replacement of batteries provided by the product manufacturer.

Spare battery availability

Regarding the specification for spare part availability in paragraph 6 of Article 11, the following additional elements are relevant for a successful battery replacement:

- The availability of physical elements (other than the spare battery itself) necessary for the battery replacement. If the fasteners associated with the disassembly and re-assembly of the battery are reusable, they can be reused for the replacement. If the fasteners or connectors are not reusable, the availability of spare ones (along with the spare battery itself) is key to the success of the replacement.
- The availability of software elements (and updates) that may be necessary for the normal operation of the battery within the appliance.

It is proposed to be clarified that the requirements of paragraph 7 do not refer to spare parts for products placed on the market before Article 11 enters into force. In order to avoid an early retirement of those products, it is proposed that spare parts for them may remain available, as they can contribute to the continuation of the product's lifetime.

Availability of spare batteries with a reasonable and non-discriminatory price for independent professionals and end users aims at enabling that battery replacements actually materialise. The price of repair has been reported as a top reason for not repairing products (European Commission et al, 2018) and according to input

from stakeholders repairs are generally carried out when the cost is below 30%-40% of the product value (Cordella et al, 2019;), even though this highly dependent on the product type and value.

Disassembly Depth

Even though not referenced in Article 11, Disassembly Depth is another established parameter in product disassembly literature, defined in European standard EN45554:2020 as well as in reparability assessment methods (e.g. Cordella et al, 2019). The concept of Disassembly Depth refers to the number of steps required to remove a part from a product. For a battery to be removable by end-users, this is a determining factor in ensuring a reasonable disassembly time. Therefore:

→ The concept of removability, refers to a reasonable number of disassembly steps, whereby a lower the number of disassembly steps indicates a higher level of removability and replaceability

3.2 Synergy with ecodesign regulation for mobile phones, cordless phones and slate tablets

Regulation (EU) 2023/1670 also sets requirements relating to the removability and replaceability of batteries (as well as for other components). The Battery Regulation explicitly allows for such specific rules under other legislation if those specific rules ensure a higher level of protection of the environment and human health. The ecodesign regulation on mobile phones and tablets requires with regard to replaceability of batteries that either the end-user has to be able to remove the battery, or that a professional repairer with generalist skills in a workshop environment is able to do so, but in the latter case the battery has also to meet higher requirements on battery endurance. Thus, the synergy between the reparability requirement (professional repairer with generalist skills in a workshop environment) and the higher endurance requirement provides a higher level of protection of the environment and human health, while there are no negative effects in that respect compared to the Battery Regulation because the batteries are still replaceable in all cases. As a consequence, paragraph 1 of Article 11 does not apply to mobile phones and tablets covered by ecodesign regulation (EU) 2023/1670.

The Ecodesign regulation on mobile phones and tablets also addresses availability of spare parts, including the battery, and the issue of software affecting the replacement of the battery, or other parts. For these issues, the Battery Regulation does not make an explicit exemption in relation to other legislation, which means that both Regulations apply at the same time.

For the availability of batteries as spare parts the Battery Regulation requires that they have to be available for five years after the last unit of an appliance model has been placed on the market, while the ecodesign regulation on mobile phones and tablets requires them in certain cases to be available for seven years after the last unit of a phone/tablet model has been placed on the market. Thus, batteries for mobile phones and tablets covered by the ecodesign Regulation have to be made available as spare parts for five years after the last unit of the mobile phone or tablet model has been placed on the market, and longer where the ecodesign Regulation requires so.

Concerning software, the ecodesign regulation on mobile phones and tablets has a specific approach requiring manufacturers using serialized parts to give non-discriminatory access for professional repairers and end-users to any software tools, firmware or similar auxiliary means needed to ensure the full functionality of spare parts and of the device (in line with the procedure laid down under Annex II.B.7 of the Regulation). This will apply as from [21 months after its entry into force]. Article 11 of the Battery Regulation will apply later, from 17 February 2027. From that date it will not be possible for batteries of smartphones and tablets to use software affecting the replacement of the battery. The ecodesign provisions of (inter alia) Annex II.B.7 will continue to apply for the other components.

4 Paragraphs 2 and 5: RR by qualified independent professionals

4.1 Concept of independent professionals

The following clarifications are proposed to address the reference to "independent professionals" in paragraphs 2 and 5 of Article 11.

"Independent professionals" are understood to be independent operators who have the technical competence and qualification to repair the product where the battery is integrated in, conduct their business on commercial premises, and comply with the applicable regulations for repairers of electrical equipment in the Member States where it operates.

In case of removability and replaceability actions on individual cells within a battery pack, the "independent professional" is understood to have the technical competence to repair the battery pack.

In case of removability and replaceability actions on products subject to type-approval under the scope of regulation (EU) No 168/2013, independent professionals are understood to be 'independent operators' as defined in regulation (EU) No 168/2013.

Compliance with the above points could be demonstrated by a reference to an official registration system as professional repairer (when such system exists in the Member States concerned), or by registration with, or training/certification by, the manufacturer of the product where the battery is integrated in (when required by national legislation).

Furthermore, the professional is understood to be covered by insurance covering liabilities resulting from its activity regardless of whether this is required by the Member State.

In all cases, battery removal and replacement (either at pack or cell level) should be performed according to the safety information on the use, removal and replacement of batteries provided by the product manufacturer.

4.2 Appliances specifically designed to operate primarily in a wet environment

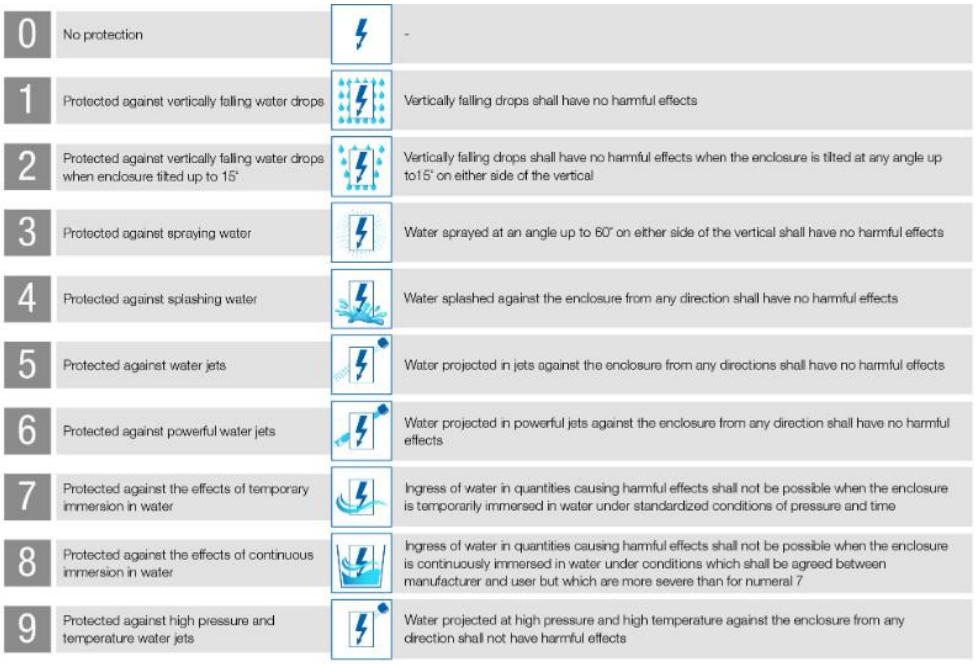
Paragraph 2 of Article 11 specifies that appliances **specifically** designed to operate **primarily** in an environment that is regularly subject to splashing water, water streams or water immersion, and that are intended to be **washable or rinseable**, are exempted from paragraph 1 and may be designed in such a way as to make the battery removable and replaceable only by qualified independent professionals. It also specifies that this derogation shall only be applicable where such derogation is required to ensure the safety of the user and the appliance. Furthermore, regulation's recital (39) specifies that "this derogation should only apply when it is not possible, by way of redesign of the appliance, to ensure the safety of the end-user and the safe continued use of the appliance after the end-user has correctly followed the instructions to remove and replace the battery".

In other words, the following specifications are identified as all being relevant criteria to consider for such appliances for the derogation to apply:

(i) "***Specifically***": The appliance is **specifically** designed to operate in the environment described;
(ii) "***Primarily***": The environment described is the **primary environment** of the appliance, as recital 39 explicitly specifies, "*for the majority of the active service of the appliance*". In other words, not just an environment in which the device may only coincidentally or circumstantially be introduced to;
(iii) "***Washable or rinseable***": the appliance is intended to be **washable or rinseable;**
(iv) ***Compromising safety***: there is evidence that battery replaceability and removability by end-users would **compromise the safety** of the user or the appliance;
(v) "***No way to redesign***": there is evidence that there is **no way to redesign** the appliance so that it safely operates in the environment described (as pointed out in recital 39 of the regulation).

The Ingress Protection (IP) rating system defined in standard IEC 60529 (specifically, the second numeral related to water as depicted in Figure 3) offers an indicative guide to identify the described environment referred to in the above-mentioned criteria..

Figure 3 Ingress Protection (IP) ratings guide for water



Source: IEC[1]

Specifically, the case of "splashing water" referenced in Article 11 of the regulation is equivalent to an IPX4 rating (class number 4 described in Figure 3), the case of "water streams" in the regulation is equivalent to IPX5 and IPX6 (classes number 5 and number 6 in Figure 3), and the case of "water immersion" in the regulation is equivalent to an IPX7 rating (class number 7 described in Figure 3).

Regarding points (ii) and (iii), a representative example of products primarily operate in such environment can be oral hygiene appliances (e.g. toothbrushes as in IEC 60335-2-52)[2], and shavers, hair clippers and epilators (as in IEC 60335-2-8)3. At the same time, by point (iv) it is understood that there may still be appliances used in wet environment that incorporate batteries which are removable and replaceable by end-users, as long as this does not compromise safety. An example can be appliances powered by batteries of general use.

4.3 Medical devices and in-vitro diagnostic medical devices

Paragraph 2 specifies that professional medical imaging and radiotherapy devices, as defined in regulation (EU) 2017/745, and in-vitro diagnostic medical devices, as defined in regulation (EU) 2017/746, may be designed in such a way as to make the battery removable and replaceable only by independent professionals.

[1] https://www.iec.ch/ip-ratings
[2] IEC 60335-2-52:2021 Household and similar electrical appliances – Safety-Part 2-52: Particular requirements for oral hygiene appliances
[3] IEC 60335-2-8:2022 Household and similar electrical appliances - Safety-Part 2-8: Particular requirements for shavers, hair clippers and similar appliances

5 Paragraph 3: Full derogations

Paragraph 3 provides reasons justifying derogation, and specifically where continuity of power supply is necessary and a permanent connection between the product and the respective portable battery is required to ensure the safety of the user and the appliance or, for products that collect and supply data as their main function, for data integrity reasons.

In order to structure the derogation guidance, the aforementioned derogations can be grouped in two categories: safety reasons and data integrity reasons described in the sections 4.1 and 4.2 respectively.

5.1 Safety considerations

Products explicitly referenced in the regulation

The proposed Batteries Regulation already specifies in Article 1 that it shall not apply to batteries in:

- equipment connected with the protection of Member States' essential security interests, arms, munitions and war material, with the exclusion of products that are not intended for specifically military purposes; and
- equipment designed to be sent into space.

Equipment and protective systems intended for use in potentially explosive atmospheres

Directive 2014/34/EU, relating to equipment and protective systems intended for use in potentially explosive atmospheres contains provisions related to enclosed structures and prevention of leaks and safe opening of such equipment, states in its Annex I:

> *1.2.3. Enclosed structures and prevention of leaks: Equipment which may release flammable gases or dusts must wherever possible employ enclosed structures only. If equipment contains openings or non-tight joints, these must as far as possible be designed in such a way that releases of gases or dusts cannot give rise to explosive atmospheres outside the equipment.*
>
> *1.2.6. Safe opening: If equipment and protective systems are in a housing or a locked container forming part of the explosion protection itself, it must be possible to open such housing or container only with a special tool or by means of appropriate protection measures.*

In this type of application and regardless of product type, a risk-averse approach is proposed with regards to removability and replaceability by associating such application with the safety reasons of the derogation.

Devices that perform life-saving and life-sustaining functions

Paragraph 2 already specifies the products which may be designed in such a way as to make the battery removable and replaceable only by independent professionals. Nevertheless, medical devices cover a wide range of products which are used in applications with different levels of criticality. The uninterrupted operation of some medical devices is key when delivering care to a patient and therefore a risk averse approach to medical devices is proposed as appropriate. They include products that perform life-saving and life-sustaining functions and therefore a risk-averse approach is considered appropriate.

The classification systems offered in Regulation (EU) 2017/745 (Article 51 and Annex VIII) and Regulation (EU) 2017/746 (Article 47 and annex VIII) can be used. The classifications use a 'risk based' system based on the vulnerability of the human body taking account of the potential risks associated with the devices.

It is considered that Class III medical devices and Class D in-vitro medical devices are associated with high risks, including, for example, the use of software intended to provide information used to take diagnostic or therapeutic decisions that may cause *"death or an irreversible deterioration of a person's state of health"*[4]. Therefore, a lack of continuity of power supply and a break of connection between the product and the respective portable battery entails a high risk of compromising the safety of the user and as such considered as relevant to the derogation as described in Art11, paragraph 3.

[4] MDCG 2020-16 rev.1 "Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746"

Additionally, and similarly to implanted devices, hearing aids constitute medical devices whose useful lifetime is dictated specifically by medical reasons (i.e. progressing hearing loss) rather than by design for battery removability and replaceability. At the same time, replaceability of the battery could pose a safety risk to the patient.

It is also worth noting that the classification is determined by the intended use. It is the intended and not the accidental use of the device that determines the device class. It is the intended purpose assigned by the manufacturer that determines the class of the device and not the class assigned to other similar products.

Furthermore, Article 2(4)(g) of Directive 2012/19/EU on Waste Electrical and Electronic Equipment excludes from its scope "medical devices and in vitro diagnostic medical devices, where such devices are expected to be infective prior to end of life, and active implantable medical devices". Therefore, those devices are also proposed to be understood as relevant for derogation from the requirements of paragraph 1. The WEEE Directive's FAQ[5] provides the examples of single use medical equipment (e.g. electrodes used to attach to a baby's head in order to monitor the health condition of the baby during birth), and medical equipment that due to national regulation shall be collected and treated via an infectious health hazard regime (clinical waste).

The rationale for the first exemption lies with the fact that if a medical device is intended to be used more than once (by one or more patients), meaning that it is not a single-use equipment, then this equipment is designed in such a way that the risk of contamination on handling is low[6].

The above proposal should be without prejudice to other requirements, related to safety or performance, set out in Regulation (EU) 2017/745 or in other Union legislation, notably the WEEE directive (as mentioned above), the Low Voltage Directive, the Product Safety Directive and the Toys Safety Directive.

5.2 Data integrity considerations

Article 11 specifies that the provisions of paragraph 1 *"shall not apply where continuity of power supply is necessary and a permanent connection between the product and the respective portable battery is required […] for products that collect and supply data as their main function, for data integrity reasons"*.

The regulatory text defines both the function, which needs to be the main function of the product (data collection and supply), as well as the specific reason justifying such derogation (data integrity). As such, it is proposed that an exemption is not considered relevant for any device that:

- delivers a data collection and supply function as an additional feature (beyond its main function), nor for any device that may contain a component which delivers a data collection and supply function.
- delivers a data collection and supply function, as a primary function, but does not pose a risk of data integrity loss, due to, for example, the presence of non-volatile memory in the device.

By means of example, the main function of a battery-powered instrument used in weather stations or in laboratories is the continuous collection of data, and this continuity is an integral part of the function deeming the continuity of power supply necessary. It is therefore an example of a product which, for data integrity reasons, a permanent connection between the product and the battery is required. Another similar case is batteries whose main function is to power a non-volatile memory itself, or deliver backup functions in the internal clock of a device, such as those found in processors, sensors and medical devices regardless of their class under regulations (EU) 2017/745 and (EU) 2017/746 (e.g. blood glucose monitors or devices for dialysis treatments). In this case as well, continuity of power supply is deemed necessary for data integrity reasons.

[5] https://ec.europa.eu/environment/pdf/waste/weee/faq.pdf

[6] WEEE2 guidance document on "Medical devices, in vitro diagnostic and active implantable medical devices ("MD, ivMD & aiMD")" published by the European WEEE Registers Network (EWRN) on October 2016 https://www.ewrn.org/fileadmin/ewrn/documents/161028_EWRN_expected_infective_MD_WEEE2_Guidance_fin.pdf

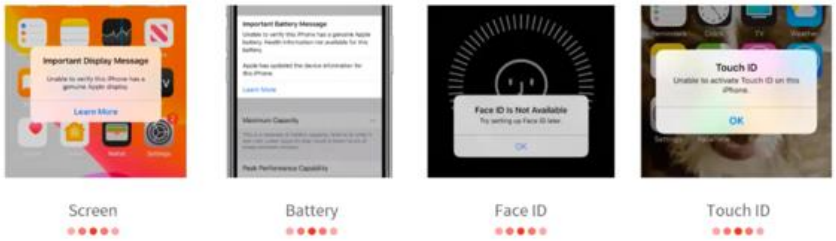
6 Paragraph 8: Software limitations

As per paragraph 6 of Article 11, software shall not be used to impede the replacement of a portable battery or LMT battery or of their key components with another compatible battery or key components.

The concept of compatible battery was discussed in section 2 above.

An example of software affecting replacement has been reported to be "part-pairing". This is made possible by serialisation of some spare parts, (including batteries) which are paired to an individual unit of a device using software. Serialisation on its own is not detrimental to repair, and can in fact be beneficial for circularity by facilitating access to historical information about a component, or for repair itself by facilitating the identification of appropriate spare parts in case of failure[7]. However, it is when serialisation leads to pairing a part to a product unit that is detrimental to repair with other parts which may be compatible. According to Dangal et al (2022), this phenomenon can be observed in various products, ranging from electronics, to household appliances, to gardening tools, and even though security is often quoted as a rationale for the pairing approach, pairing is not technically necessary to achieve adequate security. If a product component, including a battery, needs replacing during a repair, it might not be accepted, or lose some of its functionality unless remotely paired to the device again via software by the manufacturer. According to the evidence collected by the Right to Repair campaign, once a device subject to part pairing is repaired or refurbished by independent professional, customers can receive warning messages, like the ones portrayed in Figure 4 below, to inform them that the new part "isn't genuine" and even sometimes that it is not working (Alfieri and Spiliotopoulos, 2023).

Figure 4 Warning messages after replacing a part with a non-paired one



Source: Alfieri and Spiliotopoulos, 2023

Backmarket[8], a leading platform of refurbished products, has noticed an increase in aftermarket services tickets since the rise of products affected by part pairing and a share of customers returning the tickets as reported during the webinar "How software could make independent repair impossible"[9].

Software notifications to the consumer informing that a non-original spare battery is in use can be provided, however, only as long as such notifications do not affect any functionality of the device (or the compatible battery), or affect the user experience. At all times repair should not be impeded.

[7] https://www.ifixit.com/News/69320/how-parts-pairing-kills-independent-repair
[8] https://www.backmarket.com/
[9] Webinar recording available at https://youtu.be/CvCThm0tHCA

7 Summary of the analysis

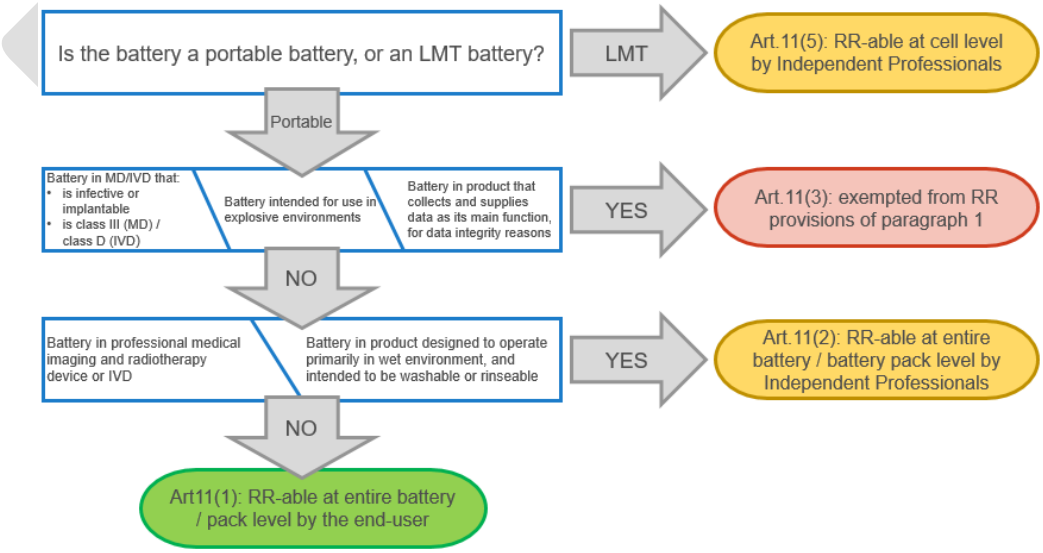
Table 1 below provides a summary of the results of this analysis.

Table 1 Summary table of analysis

Reason	Type	Application	Removability / Replaceability
Safety	Products under Dir. 2014/34/EU	Intended for use in potentially explosive atmospheres	Derogation
	Products under wet environment exposure	Specifically designed to operate primarily in an environment that is regularly subject to splashing water, water streams or water immersion, and that are intended to be washable or rinseable.	Independent professionals
Medical	Medical devices (Reg. (EU) 2017/745)	Professional medical imaging, radiotherapy devices	Independent professionals
		Class III / infective and implantable, hearing aids	Full Derogation
	In-vitro diagnostic medical devices (Reg. (EU) 2017/746)	Class A (except infective and implantable) Class B (except infective and implantable) Class C (except infective and implantable)	Independent professionals
		Class D (except infective and implantable)	Full Derogation
Data Integrity	Products that collect and supply data as their main function		Derogation
LMT			Independent professionals

The following decision tree (Figure 5) provides further visual representation of the guidance provided above.

Figure 5 Decision tree for the application of Art.11 provisions



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Cordella M, Alfieri F, Sanfelix J, (2019). Analysis and development of a scoring system for repair and upgrade of products – Final report, EUR 29711 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-01602-1, doi:10.2760/725068, JRC114337, http://dx.doi.org/10.2760/725068

Dangal, S., Balkenende, R., Faludi, J., Eisenriegler, S., Reichl, H., Haas, J., Neumerkel, A., Wild, J., Depypere, M., Opsomer, T. 2022. Design for physical durability, diagnosis, maintenance, and repair. Deliverable 4.3, PROMPT Project. https://prompt-project.eu/wp-content/uploads/2022/05/PROMPT-D4.3-TEXT-APPENDIX.pdf

Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)

European Commission, Consumers, Health, Agriculture and Food Executive Agency, Duke, C., Thorun, C., Dekeulenaer, F., et al., Behavioural study on consumers' engagement in the circular economy: final report, {CEU}, 2018, https://data.europa.eu/doi/10.2818/956512

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European Commission, Directorate-General for Environment, Stahl, H., Mehlhart, G., Gsell, M., et al., Assessment of options to improve particular aspects of the EU regulatory framework on batteries: final report, Publications Office, 2021, https://data.europa.eu/doi/10.2779/432234

IEC 60529 Degrees of protection provided by enclosures (IP code)

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC