



Office for Product
Safety & Standards

Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001

As they apply to equipment being supplied in or into Great
Britain after 1 January 2021

Guidance v2

January 2021



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Guidance

1. Introduction

This Guide is for businesses placing equipment for use outdoors on the market in Great Britain from 1 January 2021¹. If you are placing equipment for use outdoors on the market in Northern Ireland, you should read separate guidance:

<https://www.gov.uk/government/publications/noise-emission-in-the-environment-by-equipment-for-use-outdoors-regulations-2001>

This Guide is designed to help you understand the Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (referred to in this document as “the 2001 Regulations”). The 2001 Regulations set out the requirements that must be met before products can be placed on the GB market. The purpose of the legislation is to ensure that only equipment that does not exceed permissible sound power levels are placed on the GB market or put into service by requiring “responsible persons” to ensure the equipment meets the relevant requirements.

2. Legislative Background

The Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001 implemented Directive 2000/14/EC. The EU Withdrawal Act 2018 preserves the Regulations and enables them to be amended so as to continue to function effectively now the UK has left the EU. Accordingly, the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019² fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the GB market.

There is therefore one set of UK 2001 Regulations, but some of the provisions apply differently in NI for as long as the Northern Ireland Protocol is in force. References to the 2001 Regulations in this guidance are references to those Regulations as they apply in Great Britain. For guidance on placing on the Northern Ireland market, please see:

<https://www.gov.uk/government/publications/noise-emission-in-the-environment-by-equipment-for-use-outdoors-regulations-2001>

3. Scope

The 2001 Regulations apply to equipment listed in Schedules 1 and 2 of the Regulations. A full list of equipment to which the 2001 Regulations apply can be found in Annex A to this guidance.

¹ The Implementation or Transition Period officially ends at 11pm on 31 December 2020 and therefore references to 1 January 2021 should be read as meaning 11pm on 31 December 2020.

² The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 were amended by the Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 to apply to Great Britain only, and not to Northern Ireland, in support of implementing The Protocol of Ireland and Northern Ireland (“The Northern Ireland Protocol”). The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 were further amended by the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 to provide for a 24 month transition period for importer labelling (for goods from the EEA), UKCA marking, to amend the definition of “authorised representative” as well as introducing an end (in 12 months from the end of the Transition Period) to the recognition of goods meeting EU requirements, as well as introducing provisions for qualifying Northern Ireland goods.

The 2001 Regulations do not apply to the following equipment:

- a) non-powered attachments separately placed on the market or put into service except for hand-held concrete breakers and picks and those for hydraulic hammers;
- b) all equipment primarily intended for the transport of goods or persons by road or rail or by air or on waterways; or
- c) equipment specially designed and constructed for military and police purposes and for emergency services.

4. Requirements

The 2001 Regulations detail the requirements which must be met by a responsible person (the definition has been amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 – see below) before placing on the market or putting into service any equipment to which the Regulations apply.

The requirements concerning noise emission in the environment of equipment to which the 2001 Regulations apply are that the guaranteed sound power level does not exceed the applicable permissible sound power level as laid out in the table below, and the guaranteed sound power level is to be marked on the equipment.

The responsible person must ensure that the machinery is in conformity and has been UKCA marked³ and has the indication of guaranteed sound power level. The equipment must be accompanied by a declaration of conformity. Until 31 December 2022, the UKCA marking may be affixed to a label affixed to, or a document accompanying, the machinery.

Qualifying Northern Ireland goods can be placed on the GB market with the CE and CE UKNI conformity markings, see further detail in Section 9 on Qualifying Northern Ireland Goods.

5. Obligations of manufacturers

Under the 2001 Regulations, the onus to comply lies with the responsible person, being the manufacturer or their authorised representative. Where the manufacturer is not established in the UK, the obligations of the 2001 Regulations shall apply to any person placing the equipment on the GB market or putting it into service in GB.

Equipment subject to noise limits

Before placing on the market or putting into service any equipment subject to noise emission limits, the manufacturer, or his authorised representative, shall subject each type of equipment to one of the following conformity assessment procedures:

- either the internal control of production with assessment of technical documentation and periodical checking procedure referred to in Annex E of this guidance,
- or the unit verification procedure referred to in Annex F,
- or the full quality assurance procedure referred to in Annex G.

All three of the above will require the involvement of approved bodies (UK based conformity assessment bodies – for more detail see below).

³ Until 31 December 2021, machinery conforming to EU rules, including the CE marking, may be placed on the market of Great Britain.

Equipment subject to noise marking only

Before placing on the market or putting into service any equipment subject to noise marking only, the manufacturer, or their authorised representative, shall subject each type of equipment to:

- the internal control of production procedure referred to in Annex D.

The procedure under Annex D will not require the involvement of 'approved bodies'.

Noise Limits:

The guaranteed sound power level of the equipment shall not exceed the permissible sound power level as laid down in the table below.

Type of equipment	Net installed power P in kW Electric power P_{el} ^a in kW Mass of appliance m in kg Cutting width L in cm	Permissible sound power level in dB/1 pW	
		as from Stage I 3 January 2002	as from Stage II 3 January 2006
Compaction machines (vibrating rollers, vibratory plates, vibratory rammers)	$P \leq 8$ $8 < P \leq 70$ $P > 70$	108 109 $89 + 11 \lg P$	105b 106b $86 + 11 \lg P_b$
Tracked dozers, tracked loaders, tracked excavator-loaders	$P \leq 55$ $P > 55$	106 $87 + 11 \lg P$	103b $84 + 11 \lg P_b$
Wheeled dozers, wheeled loaders, wheeled excavator-loaders, dumpers, graders, loader-type landfill compactors, combustion-engine driven counterbalanced lift trucks, mobile cranes, compaction machines (non-vibrating rollers), paver-finishers, hydraulic power packs	$P \leq 55$ $P > 55$	104 $85 + 11 \lg P$	101b $82 + 11 \lg P_b$
Mobile Cranes	$P \leq 55$ $P > 55$	104 $85 + 11 \lg P$	101 c $82 + 11 \lg P$ 101c
Excavators, builders' hoists for the transport of goods, construction winches, motor hoes	$P \leq 15$ $P > 15$	96 $83 + 11 \lg P$	93 $80 + 11 \lg P$
Hand-held concrete-breakers and picks	$m \leq 15$ $15 < m < 30$ $m \geq 30$	107 $94 + 11 \lg m$ $96 + 11 \lg m$	105 $92 + 11 \lg m_b$ $94 + 11 \lg m$
Tower cranes		$98 + 1 \lg P$	$96 + 1 \lg P$
Welding and power generators	$P_{el} \leq 2$ $2 < P_{el} \leq 10$ $10 > P_{el}$	$97 + 1 \lg P_{el}$ $98 + 1 \lg P_{el}$ $97 + 1 \lg P_{el}$	$95 + 1 \lg P_{el}$ $96 + 1 \lg P_{el}$ $95 + 1 \lg P_{el}$
Compressors	$P \leq 15$ $P > 15$	99 $97 + 2 \lg P_{el}$	97 $95 + 2 \lg P_{el}$

Lawnmowers, lawn trimmers/lawn edge trimmers	$L \leq 50$	96	96
	$50 < L \leq 70$	100	98
	$70 < L \leq 120$	100	100
	$L > 120$	105	105
<p>The permissible sound power level shall be rounded up or down to the nearest integer number (less than 0.5, user lower number; greater than or equal to 0.5, user higher number)</p> <p>^a P_{eI} for welding generators: conventional welding current multiplied by the conventional load voltage for the lowest value of the duty factor given by the manufacturer</p> <p>P_{eI} for power generators: prime power according to ISO 8528-1:1993, clause 13.3.2</p> <p>b For the following types of equipment for the figures for Stage I will continue to apply for Stage II:</p> <p>Walk-behind vibrating rollers Vibratory plates (>3 kW) Vibratory rammers Dozers (steel tracked) Loaders (steel tracked >55 kW) Combustion-engine driver counterbalanced lift trucks Compacting screed paver-finishers; and Hand-held internal combustion-engine concrete-breakers and picks (15<m<30).</p> <p>c For single engine mobile cranes the figures for Stage I shall continue to apply until 3rd January 2008. After that date Stage II figures shall apply</p>			

6. Obligations of authorised representatives

Manufacturers are able to appoint authorised representatives and, where they do so, those authorised representatives will be “responsible persons” within the meaning of the Regulations.

Mandated authorised representatives for the GB market can be based in GB or Northern Ireland, but after 1 January 2021 cannot be based outside the UK. A manufacturer can only mandate an authorised representative established in the UK, under the 2001 Regulations as they apply in GB.

No GB-based authorised representatives are recognised under EU law. This means GB-based authorised representatives cannot carry out tasks on the manufacturer’s behalf for equipment being placed on the Northern Ireland or EEA markets. Therefore, a GB manufacturer selling equipment to the EEA or into Northern Ireland, who wishes to appoint an authorised representative to carry out tasks for them in respect of those products, must appoint an authorised representative based in Northern Ireland or the EEA.

An authorised representative must comply with all the duties imposed on the responsible person under the 2001 Regulations.

Any references in the 2001 Regulations to the responsible person are to be taken to include a reference to the authorised representative including in relation to penalties for failure to comply with those duties.

7. Transitional arrangements

Products placed on the market before 1 January 2021

If you have already placed an individual fully manufactured product on the EEA or the UK market (either in Northern Ireland or Great Britain) before 1 January 2021, you do not need to do anything new. These individual goods can continue to circulate on either market until they reach their end user and do not need to comply with the changes that take effect from 1 January 2021.

A fully manufactured good is 'placed on the market' when there is a written or verbal agreement (or offer of an agreement) to transfer ownership or possession or other rights in the product. This does not require physical transfer of the good.

You can usually provide proof of placing on the market on the basis of any relevant document ordinarily used in business transactions, including:

- contracts of sale concerning goods which have already been manufactured and meet the legal requirements;
- invoices; and
- documents concerning the shipping of goods for distribution.

The relevant responsible person (manufacturer, authorised representative or person placing on the market or putting into service) bears the burden of proof for demonstrating that the good was placed on the EEA or UK market before 1 January 2021.

Existing CE marked stock

The UK will allow CE marked equipment for use outdoors that has been either self-declared as compliant (where permissible) or where compliance must and has been demonstrated through assessment by an EU-recognised conformity assessment body (notified body) to be placed on the GB market until 31 December 2021.

Equipment for use outdoors lawfully placed on the market with a CE marking by 31 December 2021 can continue to circulate on the GB market after this date.

8. UKCA Marking

Assessment through third-party organisations:

From 1 January 2021, equipment that is conformity assessed by a UK approved body should be UKCA marked, not CE marked. If the conformity assessment was carried out by a UK notified body and the CE marking was affixed to the fully made product before 1 January 2021, the CE marking can still be used. But it can only be placed on the GB market and must be placed on the GB market before 31 December 2021.

Where the equipment has been assessed by an EU Notified Body, manufacturers must continue to use the CE marking. These products will be able to be placed on the GB market until 31 December 2021. Qualifying Northern Ireland goods complying with the legislation as it applies in Northern Ireland, including affixing the CE marking, may be placed on the GB market after 31 December 2021. See further detail in Section 9 on Qualifying Northern Ireland Goods.

Rules around physically affixing the new UKCA conformity marking mirror those which currently apply for the application of the CE marking although until 31 December 2022, the UKCA marking may be affixed to a label affixed to the equipment or a document accompanying the equipment, rather than being affixed to the equipment itself (even where it is otherwise possible to affix it to the equipment itself).

Self-declaration:

Responsible persons selling equipment on the GB market can affix the new UKCA marking before placing a product on the UK market. CE marking based on self-declaration of conformity by the responsible person is still possible until 31 December 2021 for the GB market, where self-declaration was previously permissible.

It will also be possible to affix both the UKCA marking and the CE marking to the same product on the basis of self-declaration, as long as the EU and GB requirements remain the same. When selling to the EU or placing on the NI market, the CE marking remains mandatory.

Further guidance on UKCA marking can be found here:

<https://www.gov.uk/guidance/using-the-ukca-marking>

9. Qualifying Northern Ireland Goods

The government has committed to providing unfettered access for qualifying Northern Ireland goods to the rest of the UK market after 1 January 2021. Products that can be placed on the market in Northern Ireland in accordance with the legislation, as it applies to Northern Ireland, can be sold in the rest of the UK without any additional approvals.

This means that products that are qualifying Northern Ireland goods can be sold in the rest of the UK if any of the following apply:

- the CE marking is lawfully applied to the good on the basis of self-declaration
- any mandatory third-party conformity assessment was carried out by an EU-recognised notified body (including a body in a country with which the EU has a relevant mutual recognition agreement) and a CE marking is affixed
- the certificate of conformity previously held by a UK approved body has been transferred to an EU-recognised notified body and a CE marking has been affixed
- any mandatory third-party conformity assessment was carried out by a UK-based body, and the good is therefore marked with the CE marking and with the new UKNI marking

This will be the case even if there are changes between the EU rules that the Northern Ireland Protocol applies to NI and the GB rules.

You can find more information about the UKNI marking here:

<https://www.gov.uk/guidance/using-the-ukni-marking>

NI businesses that are importing products from the EEA and placing them on the GB market must ensure that the relevant conformity assessment procedure has been carried out, that the technical documentation has been drawn up and that the equipment bears the CE marking.

You can find out more about qualifying Northern Ireland goods here:

<https://www.gov.uk/guidance/moving-qualifying-goods-from-northern-ireland-to-the-rest-of-the-uk>

10. Approved Bodies

The UK has established a new framework for UK based bodies to assess equipment against GB rules. Existing UK notified bodies have been granted new UK 'approved body' status and are listed on a new UK database. They do not need to seek re-appointment in order to benefit from UK approved body status. These approved bodies retain their 4-digit identification number. New approved bodies will be assigned a number by the Office for Product Safety and Standards on behalf of the Secretary of State.

Approved bodies can assess equipment for the GB market against GB requirements (which are, as yet, the same as EU requirements).

Approved bodies are conformity assessment bodies which were registered UK notified bodies before 1 January 2021, or have been approved by the Secretary of State to carry out the procedures for conformity assessment and certification for the GB market.

UK approved bodies must be established in the UK and be independent of the manufacturer. Approved bodies must examine the technical documentation and supporting evidence in respect of the product to assess the adequacy of the technical design.

Where an approved body finds that the equipment does not conform to the requirements, they must not issue a certificate of conformity and they must require the manufacturer to take corrective measures.

A register of UK Approved Bodies can be found on the UKMCAB system at the link here:

<https://www.gov.uk/uk-market-conformity-assessment-bodies>

The register also contains details of bodies in other countries such as Australia, New Zealand, Canada, Japan, and the United States of America, which the UK is designating as Approved Bodies through Mutual Recognition Agreements.

11. Enforcement

These Regulations are enforced by the Office for Product Safety and Standards on behalf of the Secretary of State for Business, Energy and Industrial Strategy.

Regulators' Code

Market surveillance authorities must continue to have regard to the Regulators' Code when developing the policies and operational procedures that guide their regulatory activities in this area. They should carry out their activities in a way that supports those they regulate to comply and grow, including choosing proportionate approaches that reflect risk.

In responding to non-compliance that they identify, regulators should clearly explain what the non-compliant item or activity is, the advice being given, actions required, or decisions taken, and the reasons for these. Unless immediate action is needed to prevent a serious breach, regulators should provide an opportunity for dialogue in relation to the advice, requirements or decisions, with a view to ensuring that they are acting in a way that is proportionate and consistent. The Secretary of State takes account of the provisions of both the Regulators' Code and the Growth Duty in exercising his regulatory functions.

A link to the Regulators' Code can be found here:

<https://www.gov.uk/government/publications/regulators-code>

Penalties

A person committing an offence under the Regulations may be liable to a penalty. Penalties can include a fine or a prison sentence of up to three months (or both) for the most serious offences. It is matter for the enforcement authority to decide what action is appropriate in each case taking into account the circumstances of the case and the enforcement authorities' own policies, operational procedures and practices in line with the Regulators Code. Should a prosecution take place, it is at the discretion of the court to decide the penalties imposed on the offender.

12. Glossary

- **Approved Body** – A conformity assessment body which has been approved by the Secretary of State or was previously a UK 'notified body' before 1 January 2021.
- **Authorised Representative** – A person appointed by a manufacturer to perform specific tasks for the manufacturer. From 1 January 2021, authorised representatives for the GB market must be based in the UK. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly.
- **Declaration of conformity** – A document prepared by the manufacturer which must detail the following:
 - the specific product to which the declaration is referring; and
 - the name and address of the manufacturer and, where applicable, their authorised representative
- This declaration must be kept by the manufacturer for a period of ten years from the date on which the product was placed on the GB market. A copy of this declaration must be made available to the enforcing authority within 28 days of placing the product on the GB market.
- **Responsible person** – The manufacturer or their authorised representative, or if neither are in the UK then the person placing on the GB market or putting into service in GB.
- **UKCA Marking** – The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods (including equipment for use outdoors) being placed on the GB market, in place of the CE marking which is the conformity marking used in Northern Ireland and the European Union.
- **UKNI Marking** (also known as the UK(NI) indication) – The UKNI marking is a new marking applied in addition to the CE marking, where a good requiring mandatory third-party conformity assessment has been tested against EU requirements by a UK body. The UKNI marking applies when placing such products on the Northern Ireland market. Under the Government's unfettered access commitments, products lawfully marked with the UKNI marking can also be placed on the GB market if they are also qualifying Northern Ireland goods.

ANNEXES

Annex A Equipment to which the 2001 Regulations as amended apply:

Equipment subject to noise limits:

Builders' hoists for the transport of goods (combustion-engine driven)
Compaction machines (only vibrating and non-vibrating rollers, vibratory plates and vibratory rammers)
Compressors (<350 kW)
Concrete-breakers and picks, hand-held
Construction winches (combustion-engine driven)
Dozers (<500 kW)
Dumpers (<500 kW)
Excavators, hydraulic or rope-operated (<500 kW)
Excavator-loaders (<500 kW)
Graders (<500 kW)
Hydraulic power packs
Landfill compactors, loader-type with bucket (<500 kW)
Lawnmowers (excluding agricultural and forestry equipment, and multi-purpose devices, the main motorised component of which has an installed power of more than 20 kW)
Lawn trimmers/lawn edge trimmers
Lift trucks, combustion-engine driven, counterbalanced (excluding 'other counterbalanced lift trucks' with a rated capacity of not more than 10 tonnes)
Loaders (<500 kW)
Mobile cranes
Motor hoes (<3 kW)
Paver-finishers (excluding paver-finishers equipped with a high-compaction screed)
Power generators (<400 kW)
Tower cranes
Welding generators

Equipment subject to noise marking only:

Aerial access platforms with combustion engine
Brush cutters
Builders' hoists for the transport of goods (with electric motor)
Building site band saw machines
Building site circular saw benches
Chain saws, portable
Combined high pressure flushers and suction vehicles
Compaction machines (explosion rammers only)
Concrete or mortar mixers
Construction winches (with electric motor)
Conveying and spraying machines for concrete and mortar
Conveyor belts
Cooling equipment on vehicles
Drill rigs
Equipment for loading and unloading tanks or silos on trucks
Glass recycling containers
Grass trimmers /grass edge trimmers

Hedge trimmers
High pressure flushers
High pressure water jet machines
Hydraulic hammers
Joint cutters
Leaf blowers
Leaf collectors
Lift trucks, combustion-engine driven, counterbalanced (only 'other counterbalanced lift trucks' with a rated capacity of not more than 10 tonnes)
Mobile waste containers
Paver finishers (equipped with a high-compaction screed)
Piling equipment
Pipelayers
Piste caterpillars
Power generators (> 400 kW)
Power sweepers
Refuse collection vehicles
Road milling machines
Scarifiers
Shredders/chippers
Snow-removing machines with rotating tools (self-propelled, excluding attachments)
Suction vehicles
Trenchers
Truck mixers
Water pump units (not for use under water)

**Definitions for each type of equipment can be found in Schedule 4 of the Regulations.*

Annex B Declaration of Conformity

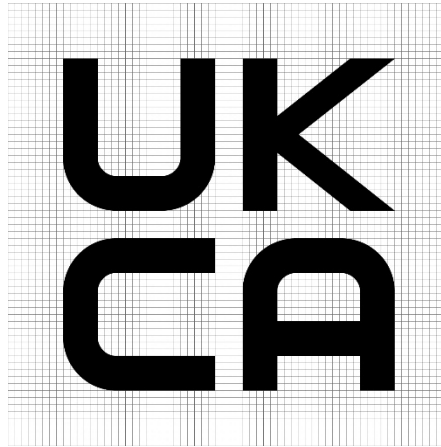
The declaration of conformity must contain the following particulars:

- name and address of the manufacturer or his authorised representative established in the UK
- name and address of the person who keeps the technical documentation
- description of the equipment
- conformity assessment procedure followed and, where appropriate, name and address of the approved body involved
- measured sound power level on an equipment representative for this type
- guaranteed sound power level for this equipment
- a reference to the 2001 Regulations
- the declaration that the equipment conforms to the requirements of the 2001 Regulations
- where appropriate, the declaration of conformity and references of other enactments applied
- the place and date of the declaration; and
- particulars of the signatory authorised to sign the legally binding declaration for the manufacturer or his authorised representative.

This declaration must be kept by the manufacturer for a period of ten years from the date on which the product was placed on the GB market. A copy of this declaration must be made available to the enforcing authority within 28 days of placing the product on the GB market by e-mailing it to: noisedeclarations@beis.gov.uk.

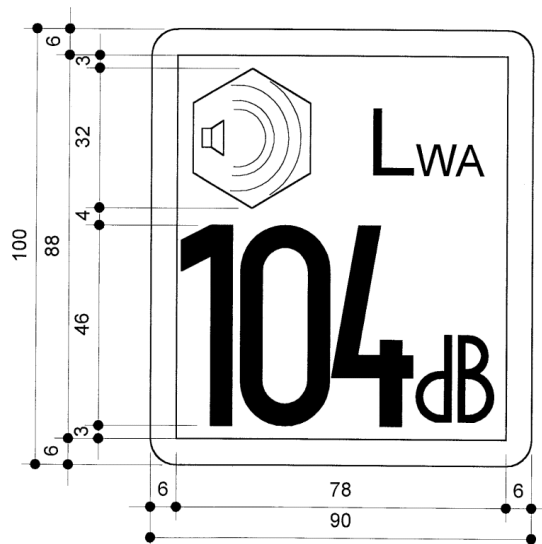
Annex C Models of the UK Marking of Conformity and of the Indication of the Guaranteed Sound Power Level

The UK conformity marking must consist of the initials 'UKCA' taking the following form:



If the UK marking is reduced or enlarged according to the size of the equipment the proportions given in the above drawing must be respected. The various components of the UK marking must have substantially the same vertical dimension which may not be less than 5 mm.

The indication of the guaranteed sound power level must consist of the single number of the guaranteed sound power in dB, the sign L_{WA} and a pictogram taking the following form:



If the indication is reduced or enlarged according to the size of the equipment, the proportions given in the above drawing must be respected. However, the vertical dimension of the indication should, if possible, not be less than 40 mm.

Annex D Internal Control of Production

1. This Annex describes the procedure whereby the manufacturer, or their authorised representative, who carries out the obligations laid down in point 2, ensures and declares that the equipment concerned satisfies the requirements of the 2001 Regulations. The manufacturer, or their authorised representative, must affix the UKCA marking, or, until 31 December 2021, the CE marking of conformity and the indication of the guaranteed sound power level as required in Regulation 7(2)(c), 11 and schedule 7 of the 2001 Regulations to each piece of equipment and draw up a written declaration of conformity as required in Regulation 7(2)(d) and Schedule 5. Until 31 December 2022, the UKCA marking may be affixed to a label or a document accompanying the equipment.
2. The manufacturer, or their authorised representative, must draw up the technical documentation described in point 3 and they must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant authorities for inspection purposes. The manufacturer, or their authorised representative, may entrust another person to keep the technical documentation. In this case they have to include the name and address of this person in the declaration of conformity.
3. The technical documentation must enable the conformity of the equipment with the requirements of the 2001 Regulations to be assessed. It must contain at least the following information:
 - name and address of the manufacturer or their authorised representative;
 - a description of the equipment;
 - make;
 - trade name;
 - type, series and numbers;
 - the technical data relevant for the identification of the equipment and the assessment of its noise emission, including, if appropriate, schematic drawings and any description and explanation necessary for their understanding;
 - the reference to the 2001 Regulations;
 - the technical report of noise measurements carried out in accordance with the provisions of the 2001 Regulations; and
 - the technical instruments applied and the results of the evaluation of the uncertainties due to production variation and their relation to the guaranteed sound power level.
4. The manufacturer must take all measures necessary in order that the manufacturing process ensures continuing compliance of the manufactured equipment with the technical documentation referred to in points 2 and 3 and with the requirements of the 2001 Regulations.

Annex E Internal Control of Production with Assessment of Technical Documentation and Periodical Checking

1. This Annex describes the procedure whereby the manufacturer, or their authorised representative, who carries out the obligations laid down in points 2, 5 and 6 ensures and declares that the equipment concerned satisfies the requirements of these Regulations. The manufacturer, or their authorised representative, must affix the UKCA marking or, until 31 December 2021, the CE marking of conformity and the indication of the guaranteed sound power level as required in Regulation 7(2)(c), 11 and Schedule 7 of the 2001 Regulations to each equipment and draw up a written declaration of conformity as required in Regulation 7 (2)(d) and Schedule 5. Until 31 December 2022, the UKCA marking may be affixed to a label or a document accompanying the equipment.
2. The manufacturer, or their authorised representative, must draw up the technical documentation described in point 3 and must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities for inspection purposes. The manufacturer, or their authorised representative, may entrust another person to keep the technical documentation. In this case, they must include the name and address of this person in the declaration of conformity.
3. The technical documentation must enable the conformity of the equipment with the requirements of the 2001 Regulations to be assessed. It must contain at least the following information:
 - name and address of the manufacturer or their authorised representative
 - a description of the equipment
 - make
 - trade name
 - type, series and numbers
 - the technical data relevant for the identification of the equipment and the assessment of its noise emission, including, if appropriate, schematic drawings and any description and explanation necessary for their understanding
 - the reference to the 2001 Regulations
 - the technical report of noise measurements carried out in accordance with the provisions of these Regulations; and
 - the technical instruments applied and the results of the evaluation of the uncertainties due to production variation and their relation to the guaranteed sound power level.
4. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured equipment with the technical documentation referred to in points 2 and 3 and with the requirements of the 2001 Regulations.

Evaluation by the approved body prior to placing on the market

5. The manufacturer, or their authorised representative, shall present a copy of his technical documentation to an approved body of their choice before the first item of equipment is placed on the GB market or put into service.

6. If there are doubts about the plausibility of the technical documentation, the approved body shall inform accordingly the manufacturer or their authorised representative in the UK, and, if need be, carry out, or have carried out, modifications of the technical documentation, or possibly tests deemed necessary.
7. After the approved body has issued a report confirming that the technical documentation satisfies the provisions of the 2001 Regulations, the manufacturer or their authorised representative established in the UK may affix the UKCA marking, or, until 31 December 2021, the CE marking to the equipment and issue an declaration of conformity in accordance with Regulations 7(2)(c) and (d) , 11 and schedules 5 and 7 of the 2001 Regulations, for which they will bear complete responsibility. Until 31 December 2022, the UKCA marking may be affixed to a label or a document accompanying the equipment.

Evaluation by the approved body during production

8. The manufacturer, or their authorised representative established in the UK, shall further involve the approved body in the production phase according to one of the following procedures to be chosen by the manufacturer or their authorised representative:
9. The approved body shall carry out periodical checks to verify continuing compliance of the manufactured equipment with the technical documentation and with the requirements of the 2001 Regulations; in particular, the approved body shall concentrate on:
 - a. the correct and complete marking of the equipment according to Regulation 7(2)(c), 11 and schedule 7 of the 2001 Regulations
 - b. issuing of the declaration of conformity according to Regulation 7(2)(d) and schedule 5 of the 2001 Regulations; and
 - c. the technical instruments applied and the results of the evaluation of the uncertainties due to production variation and their relation to the guaranteed sound power level.
10. The manufacturer, or their authorised representative established in the UK, shall give the approved body free access to all the internal documentation supporting these procedures, the actual results of the internal audits and the corrective actions which have been taken, if any.
11. Only if the above checks give unsatisfactory results shall the approved body carry out noise tests, which, upon its own judgement and experience, may be simplified or completely carried out according to the provisions laid down in Annex III of the 2001 Regulations for the relevant type of equipment.
12. The approved body shall carry out or have carried out product checks at random intervals. An adequate sample of the final equipment, chosen by the approved body, must be examined and appropriate noise tests as set out in Annex III of the 2001 Regulations, or equivalent tests, must be carried out to check the conformity of the product with the relevant requirements of the Regulations. The product checking must include the following aspects:
 - a. the correct and complete marking of the equipment according to Regulation 7(2)(c), 11 and schedule 7 of the 2001 Regulations
 - b. issuing of the declaration of conformity according to Regulation 7(2)(d) and schedule 5 of the 2001 Regulations.

13. In both procedures, the frequency of the checks shall be defined by the approved body according to the results of previous evaluations, the need to monitor corrective actions and further guidance for the frequency of the checks that may be given by the yearly production and the general reliability of the manufacturer to maintain the guaranteed values; however, a check shall be carried out at least once every 3 years.
14. If there are doubts about the plausibility of the technical documentation or the adherence during production, the approved body shall inform accordingly the manufacturer, or their authorised representative.

Annex F Unit Verification

1. This Annex describes the procedure whereby the manufacturer, or their authorised representative, ensures and declares that the equipment which has been issued with the certificate referred to in point 4 conforms to the requirements of 2001 Regulations as amended. The manufacturer, or their authorised representative, must affix the UKCA marking, or until 31 December 2021, the CE marking supplemented by the information as required in Regulation 7(2)(c), 11 and schedule 7 of the 2001 Regulations to the equipment and draw up the declaration of conformity referred to in Regulation 7(2)(d) and Schedule 5 of the Regulations. Until 31 December 2022, the UKCA marking may be affixed to a label or a document accompanying the equipment.
2. The application for a unit verification must be lodged by the manufacturer or their authorised representative with an approved body chosen by them.
3. This application must include:
 - the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address in addition
 - a written declaration that the same application has not been lodged with any other approved body
 - a technical documentation conforming to the requirements set below:
 - a description of the equipment
 - trade name
 - type, series and number
 - the technical data relevant for the identification of the equipment and the assessment of its noise emission, including, if appropriate, schematic drawings and any description and explanation necessary for their understanding; and
 - the reference to the 2001 Regulations.
4. The approved body must:
 - examine whether the equipment has been manufactured in conformity with the technical documentation
 - agree with the applicant the location where, in accordance with the 2001 Regulations, the noise tests will be carried out and
 - in accordance with the 2001 Regulations, carry out or have carried out the necessary noise tests
5. Where the equipment meets the provisions of the 2001 Regulations, the approved body must issue a certificate of conformity to the applicant as described in Schedule 12.
6. The manufacturer, or their authorised representative, must keep with the technical documentation copies of the certificate of conformity for a period of 10 years from the date on which the equipment is placed on the GB market.

Annex G Full Quality Assurance

1. This Annex describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the equipment concerned satisfies the requirements of the 2001 Regulations as amended. The manufacturer, or their authorised representative, must affix the UKCA marking, or, until 31 December 2021, the CE marking supplemented by the information as required in Regulation 7(2)(c), 11 and schedule 7 of the 2001 Regulations to each product and draw up the written declaration of conformity referred to in Regulation 7(1)(d) and Schedule 5 of the Regulations. Until 31 December 2022, the UKCA marking may be affixed to a label or a document accompanying the equipment.
2. The manufacturer must operate an approved quality assurance system for design, manufacture and final product inspection and testing as specified in point 3 and shall be subject to surveillance as specified in point 4.

Quality assurance system

3. The manufacturer must lodge an application for assessment of his quality assurance system with an approved body of their choice.
4. The application must include:
 - all relevant information for the product category envisaged, including technical documentations of all equipment already in phase of design or production that must contain at least the following information:
 - name and address of the manufacturer or their authorised representative
 - a description of the equipment
 - make
 - trade name
 - type, series and numbers
 - the technical data relevant for the identification of the equipment and the assessment of its noise emission, including, if appropriate, schematic drawings and any description and explanation necessary for their understanding
 - the reference to the 2001 Regulations
 - the technical report of noise measurements carried out in accordance with the provisions of the 2001 Regulations and
 - the technical instruments applied and the results of the evaluation of the uncertainties due to production variation and their relation to the guaranteed sound power level.
 - a copy of the declaration of conformity.
 - the documentation concerning the quality assurance system.
5. The quality assurance system must ensure compliance of the product with the requirements of the Regulations that apply to it.
6. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality assurance system documentation must permit a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

7. It must contain in particular an adequate description of:
 - the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality
 - the technical documentation to be drawn up for each product, containing at least the information indicated in point 3.1 for the technical documentations mentioned there
 - the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the equipment category covered
 - the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used
 - the examinations and test that will be carried out before, during and after manufacture, and the frequency with which they will be carried out
 - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned etc.
 - the means to monitor the achievement of the required design and product quality and the effective operation of the quality assurance system.
8. The approved body must assess the quality assurance system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with these requirements in respect of quality assurance systems that implement EN ISO 9001.
9. The auditing team must have at least one member with experience as an assessor in the equipment technology concerned. The assessment procedure must include an assessment visit to the manufacturer's premises.
10. The decision must be notified to the manufacturer. The notification must contain the conclusion of the examination and the reasoned assessment decision.
11. The manufacturer must undertake to fulfil the obligations arising out of the quality assurance system as approved and to maintain it in an adequate and efficient manner.
12. The manufacturer or their authorised representative shall keep the approved body that has approved the quality assurance system informed of any intended updating of the quality assurance system.
13. The approved body must evaluate the modifications proposed and decide whether the modified quality assurance system will still satisfy the requirements referred to in point 3.2 or whether a re-assessment is required.
14. It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

15. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality assurance system.

16. The manufacturer must allow the approved body entrance for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:
 - the quality assurance system documentation
 - the quality records as foreseen by the design part of the quality assurance system, such as results of analyses, calculations, tests, etc. and
 - the quality records as foreseen by the manufacturing part of the quality assurance system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned etc.
17. The approved body shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality assurance system and must provide an audit report to the manufacturer.
18. Additionally, the approved body may pay unexpected visits to the manufacturer. During such visits, the approved body may carry out, or cause to be carried out, tests to verify that the quality assurance system is functioning correctly, if necessary. The approved body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.
19. The manufacturer must, for a period ending at least 10 years after the last equipment has been manufactured, keep at the disposal of the relevant authorities:
 - the documentation referred to in the second indent of point 3.1 of this Annex
 - the updating referred to in the second paragraph of point 3.4 and
 - the decisions and reports from the approved body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.
20. Each approved body must give the other approved bodies the relevant information concerning the quality assurance system approvals issued and withdrawn.

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