



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 Northern  
Ireland

## Guidance v6

November 2023



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# Guidance

## 1. Introduction

This Guide is for businesses placing equipment for use outdoors on the market in Northern Ireland.

Under the terms of the Windsor Framework<sup>1</sup>, Northern Ireland (“NI”) aligns with relevant EU rules (in Annex 2) relating to the placing on the market of manufactured goods. Equipment for use outdoors placed on the NI market must therefore follow UK law as it applies to NI. The relevant law is the Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001, which apply across the UK, but some of the provisions apply differently in NI so that they continue to implement in NI the Directive 2000/14/EC relating to the noise emission in the environment by equipment for use outdoors.

This Guide is designed to help you comply with The Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001, as they apply in NI. References to “The 2001 Regulations” are references to The Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001, as they apply in NI.

The Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001 set out the essential requirements that must be met before products can be placed on the NI market. The purpose of the legislation is to ensure that only equipment that does not exceed permissible sound power levels is placed on the NI market or put into service by requiring “responsible persons” to ensure the equipment meets the relevant requirements.

Since 16 July 2021, the EU Regulation on Market Surveillance 2019/1020 (referred to as “MSC” in this document) has replaced the market surveillance provisions in the Regulation on Accreditation and Market Surveillance 765/2008. Under the terms of the Windsor Framework, EU rules on goods apply in Northern Ireland, including MSC, which will be directly applicable in NI and applies in addition to the 2011 Regulations. MSC does not apply in Great Britain.

Article 4 of MSC requires that an economic operator responsible for compliance must be based in the EU (or NI) in order to lawfully place certain products on the market, including equipment for use outdoors. This responsible economic operator must fulfil certain compliance tasks. This Guide summarises key requirements of Article 4, but detailed guidance is available here:

<https://www.gov.uk/government/publications/placing-certain-products-on-the-northern-ireland-market>

Equipment for use outdoors placed on the Great Britain (“GB”) market (GB comprises England, Scotland and Wales) must follow the separate rules for the GB market. If you are placing equipment for use outdoors on the market in GB, you should read the relevant separate guidance:

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

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<sup>1</sup> The “Windsor Framework” has the same meaning as set out in [Joint Declaration No 01/2023](#) by the United Kingdom of Great Britain and Northern Ireland and the European Union in the Withdrawal Agreement Joint Committee on the Windsor Framework on 24 March 2023.

The government is committed to providing unfettered access for qualifying NI goods to the rest of the UK market. Equipment that can be placed on the market in NI in accordance with the 2001 Regulations, as they apply to NI, can be sold in the rest of the UK without any additional approvals. The arrangements are explained in detail in the separate guidance for placing equipment for use outdoors on the market in GB.

## 2. Legislative Background

The Noise Emission in the Environment by Equipment for Use Outdoors Regulations 2001 implemented Directive 2000/14/EC.

The Directive continues to apply in respect of NI under the terms of the Windsor Framework. However, the 2001 Regulations (as they apply in NI) also implement parts of the Windsor Framework which have particular provisions in them, recognising that the UK has left the EU.

There is therefore one set of UK 2001 Regulations, but some of the provisions apply differently in NI and GB. References to the 2001 Regulations in this guidance are references to those Regulations as they apply in NI.

The 2001 Regulations were amended by the Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 and the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 to give effect to the Windsor Framework as it relates to the placing on the NI market of equipment for use outdoors<sup>2</sup>.

## 3. Scope

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

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

The 2001 Regulations do not apply to equipment placed on the market before July 2001, and there was a further limited exemption up to 2 January 2002.

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<sup>2</sup> In 2019, the 2001 Regulations were amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 to fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the UK market. The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 were then 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 Windsor Framework.

## 4. Requirements

### The 2001 Regulations

The 2001 Regulations detail the requirements which must be met by a responsible person (defined, and the definition has been amended by the 2019 Amendment Regulations – see below) before placing on the market or putting into service any equipment to which the 2001 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 appropriate conformity assessment procedure has been completed. The equipment must be accompanied by a declaration of conformity.

### MSC

#### Responsible economic operator

If equipment for use outdoors is offered for sale or supply to NI (or EU) consumers, it is considered to be placed on the EEA market. Article 4 requires that a responsible economic operator must be based in NI (or the EU) to carry out certain compliance tasks in respect of that equipment. This can be the manufacturer, an importer, a manufacturer's authorised representative, or a fulfilment service. They must carry out the compliance tasks in Article 4 and their contact details must be indicated on the product or on its packaging, the parcel or an accompanying document.

<https://www.gov.uk/government/publications/placing-certain-products-on-the-northern-ireland-market>

## 5. Obligations of manufacturers

### The 2001 Regulations

Under the 2001 Regulations, the onus to comply lies with the responsible person, being the manufacturer or their authorised representative. Where neither the manufacturer nor their authorised representative is established in NI or the European Economic Area (EEA), the obligations of the 2001 Regulations shall apply to any person placing the equipment on the market or putting it into service in NI.

#### Equipment subject to noise limits

Before placing on the NI 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 EU notified bodies (or GB based conformity assessment bodies if only placing the equipment on the NI market – for more detail see below).

### Equipment subject to noise marking only

Before placing on the NI 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 'notified 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 $P_{el}$ <sup>a</sup> 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><sup>a</sup> <math>P_{eI}</math> 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><math>P_{eI}</math> 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 (&gt;3 kW)  Vibratory rammers  Dozers (steel tracked)  Loaders (steel tracked &gt;55 kW)  Combustion-engine driver counterbalanced lift trucks  Compacting screed paver-finishers and  Hand-held internal combustion-engine concrete-breakers and picks (15&lt;m&lt;30).</p> <p>c For single engine mobile cranes the figures for Stage I shall continue to apply until 3<sup>rd</sup> January 2008. After that date Stage II figures shall apply</p>			

## MSC

If equipment for use outdoors is offered for sale or supply to NI (or EU) consumers, it is considered to be placed on the EEA market. Article 4 requires that a responsible economic operator must be based in NI (or the EU) to carry out certain compliance tasks in respect of that machinery. This can be the manufacturer, the importer, a manufacturer's authorised representative, or a fulfilment service. The responsible economic operator must:

1. **Keep documentation:** Verify that the EU declaration of conformity or declaration of performance and technical documentation have been drawn up, keep the declaration of conformity or declaration of performance at the disposal of market surveillance authorities for 10 years and ensure that the technical documentation can be made available to those authorities upon request.
2. **Provide documentation:** If a reasoned request is made by a market surveillance authority, provide them with all information and documentation necessary to demonstrate the conformity of the product.
3. **Notify risk:** If there is reason to believe a product presents a risk, inform the market surveillance authority.
4. **Cooperate:** Cooperate with market surveillance authorities, including requests to take appropriate corrective action. If that is not possible, mitigate the risks presented by the product when they believe the product presents a risk or are requested to do so by the market surveillance authorities.

The contact details of the responsible economic operator must be indicated on the product or on its packaging, the parcel or an accompanying document.



## **6. Obligations of authorised representatives**

A manufacturer can appoint an authorised representative to perform certain tasks on their behalf.

An authorised representative appointed by a manufacturer to represent him in either the NI or EEA markets cannot be based in GB. This means that GB based authorised representatives cannot carry out tasks on the manufacturer's behalf for products being placed on the NI or EEA markets.

An authorised representative based in NI can, under the 2001 Regulations as they apply in NI, carry out tasks on the manufacturer's behalf for products placed on the NI or EEA markets.

An authorised representative must comply with all the duties imposed on the manufacturer under the 2001 Regulations that they are appointed for and mandated in writing by the manufacturer to perform.

A manufacturer remains responsible for the proper performance of any obligations the authorised representative performs on their behalf.

Any references in the 2001 Regulations to the manufacturer 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. Products placed on the market before 1 January 2021**

If you placed an individual fully manufactured product on the EEA or the UK market (either in NI or GB) before 1 January 2021, you do not need to take any additional action. 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 took 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
- 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 market before 1 January 2021.

## **8. Conformity Marking**

Where equipment for use outdoors is being placed on the NI market, and the manufacturer chooses to have it conformity assessed by an EU recognised body, the marking for the NI and EEA markets continues to be the CE marking.



The CE marking can continue to be used for the GB market<sup>3</sup>, as long as all the other rules have been met.

Since 1 January 2021, where the manufacturer chooses to have the equipment conformity assessed by a UK notified body, the CE marking must be accompanied by the UKNI marking (also known as the UK(NI) indication). Products with the UKNI marking cannot be placed on the EEA market.

There is separate guidance on when and how to use the UKNI marking:

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

## 9. Qualifying Northern Ireland Goods

The government is committed to providing unfettered access for qualifying NI goods to the rest of the UK market. Equipment for use outdoors that can be placed on the NI market in accordance with the 2001 Regulations, can be sold in the rest of the UK without any additional approvals. The guide to placing equipment for use outdoors on the GB market has further details on these arrangements.

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. Notified Bodies

Notified Bodies are independent organisations notified to the European Commission to carry out the procedures for conformity assessment and certification set out in the 2001 Regulations.

From 1 January 2021, all UK Notified Bodies have remained Notified Bodies for the purpose of CE marking products for the NI market. When these UK bodies are used for mandatory conformity assessment activity, then the manufacturer will need to affix both the CE and the UKNI markings. A product with both the CE and the UKNI markings cannot then be placed on the EEA market.

There is separate guidance on when and how to use the UKNI marking online at:

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

A list of EU Notified Bodies can be found on the [NANDO](#) website. If a manufacturer uses a Notified Body from this list, then they apply only the CE marking to their product (not the both the CE and the UKNI markings).

A list of UK Notified Bodies is available here:

<https://find-a-conformity-assessment-body.service.gov.uk/>

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<sup>3</sup> On 24 August 2021 the Government announced the transition period for UKCA marking would be extended until 31 December 2022. The Product Safety and Metrology etc (Amendment) Regulations 2021 gave effect to this. On 14 November 2022 the Government announced it would be extending this until 31 December 2024. The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (SI 2022/1393) give effect to this. On 1 August 2023, the UK Government announced its intention to introduce legislation to extend recognition of goods that meet EU requirements (including the CE marking), indefinitely, beyond 2024 for many products. This will mean that certain goods that meet EU requirements can be placed on the GB market. These updates apply to the 18 regulations that fall under the Department for Business and Trade (DBT).

## 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 their 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 for the most serious offences or both. 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, and the economic operator is found to be in breach, it is at the discretion of the court to decide the penalties imposed on the offender.

## 12. Where to find guidance about Directive 2000/14/EC

You can find further and more detailed guidance on Directive 2000/14/EC here:

[https://ec.europa.eu/growth/sectors/mechanical-engineering/noise-emissions\\_en](https://ec.europa.eu/growth/sectors/mechanical-engineering/noise-emissions_en)

## 13. Glossary

- **Approved Body** – A conformity assessment body which has been approved by the Secretary of State or was a UK 'Notified Body' prior to 1 January 2021 able to carry out conformity assessment of products with a view to UKCA marking. They are not recognised by the EU (unless they have a presence in the EU) and cannot approve CE marking.
- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. An authorised representative can be based anywhere in the EEA or NI, but cannot be based in GB, in respect of products being placed on the NI market. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly.

- **CE marking** – the CE marking alone can be placed on products which are intended for the EEA or NI markets and have either been conformity assessed by an EU Notified Body or, where the Regulations permit, have been demonstrated and declared by the manufacturer as meeting the essential health and safety requirements.
- **Enforcing Authority** – 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.
- **EU Declaration of Conformity**– A document prepared by the manufacturer which must detail, amongst other things, 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 NI market. A copy of this declaration must be made available to the enforcing authority and to the European Commission within 28 days of placing the product on the market.

- **Fulfilment service** – A natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved. This does not include postal, parcel or freight services.<sup>4</sup>
- **Manufacturer** – A person who manufactures equipment for use outdoors or has it designed or manufactured and markets that product under their name or trademark.
- **Notified Body** – A conformity assessment body based in the EEA which has been approved by an EEA Member State to carry out conformity assessment for placing products on the EEA and NI markets; or a conformity assessment body that is based in the UK and has been approved by the Secretary of State, including bodies which were notified bodies whilst the UK followed EU rules. If these UK based Notified Bodies are used, the CE marking must be accompanied by the UKNI marking and cannot be placed on the EEA market (just the NI market, or, where it is also a qualifying NI good, the GB market).
- **Responsible person** – The manufacturer or their authorised representative or, if neither are in the UK, then the person placing on the market or putting into service in the UK.
- **UKCA marking** –The UK Conformity Assessed (UKCA) marking is the new UK conformity marking used for certain goods being placed on the GB market, in place of the CE marking, which is the conformity marking used in the European Union. Products being placed on the NI market cannot be UKCA marked and must continue to be CE marked, and UKNI marked if assessed by a UK notified body. There are special arrangements in place to ensure NI's unfettered access to the rest of the UK.

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<sup>4</sup> Fulfilment service is defined in Article 3 of MSC and for the purposes of MSC only is considered an economic operator. There are no specific obligations on fulfilment services under the 2001 Regulations.

- **UKNI marking** (also known as the UK(NI) indication) – The UKNI marking must be used along with the CE marking if manufacturers wish to use a UK Notified Body for conformity assessment for products to be placed on the NI market. The UKNI marking allows the product to be placed on the NI market (and, under the Government’s unfettered access commitments, where the product is also a qualifying NI good, on the GB market), but not the EEA market.

## 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 EU Declaration of Conformity**

The EU 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 notified 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 as amended
- the declaration that the equipment conforms to the requirements of the 2001 Regulations
- where appropriate, the EU 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.



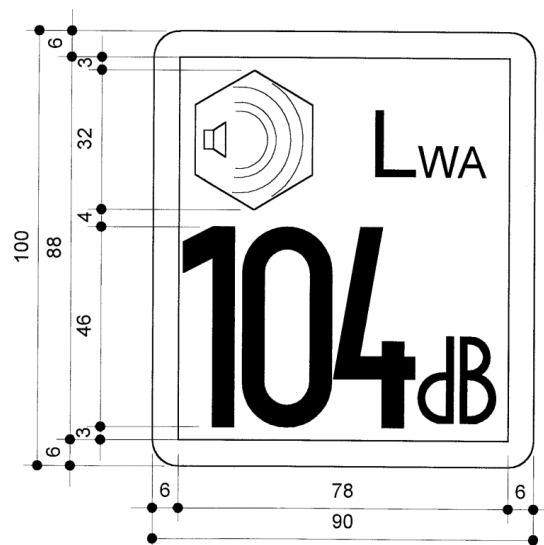
## Annex C Models of the UKNI Marking of Conformity and of the Indication of the Guaranteed Sound Power Level

The UK(NI) indication consists of the initials UKNI 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 CE marking or the CE and UKNI markings 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 EU Declaration of Conformity as required in Regulation 7(2)(d) and Schedule 5.
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 CE marking or the CE and UKNI markings, 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 EU Declaration of Conformity as required in Regulation 7 (2)(d) and Schedule 5.
2. The manufacturer, or their authorised representative, must draw up the technical documentation described in point 3 and he 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 he has 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 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 notified body prior to placing on the market**

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

6. If there are doubts about the plausibility of the technical documentation the notified 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 notified body has issued a report confirming that the technical documentation satisfies the provisions of the 2001 Regulations, the manufacturer or their authorised representative may affix the CE marking or both the CE and UKNI markings, and issue an EU Declaration of Conformity in accordance with Regulations 7(2)(c) and (d), 11 and schedules 5 and 7 of the 2001 Regulations, for which he will bear complete responsibility.

#### **Evaluation by the notified 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 his authorised representative:
9. The notified body shall carry out periodical checks in order to verify continuing compliance of the manufactured equipment with the technical documentation and with the requirements of the 2001 Regulations; in particular, the notified 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 EU 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 notified 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 notified 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 as amended for the relevant type of equipment.
12. The notified body shall carry out or have carried out product checks at random intervals. An adequate sample of the final equipment, chosen by the notified 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 EU 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 notified 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 notified 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 CE marking, or both the CE and UKNI markings, 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 EU Declaration of Conformity referred to in Regulation 7(2)(d) and Schedule 5 of the Regulations.
2. The application for a unit verification must be lodged by the manufacturer or their authorised representative with a notified 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, his name and address in addition
  - a written declaration that the same application has not been lodged with any other notified 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 notified 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 notified 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 NI 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 CE marking, or both the CE and the UKNI markings, 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 EU Declaration of Conformity referred to in Regulation 7(1)(d) and Schedule 5 of the Regulations.
2. The manufacturer must operate a notified 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 notified 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 notified body that has approved the quality assurance system informed of any intended updating of the quality assurance system.
13. The notified 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 notified 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 notified 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 notified 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 notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may carry out, or cause to be carried out, tests to verify that the quality assurance system is functioning correctly, if necessary. The notified 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 notified body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.
20. Each notified body must give the other notified bodies the relevant information concerning the quality assurance system approvals issued and withdrawn.

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