



# Product standards

## **Noise emission in the environment by equipment for use outdoors**

**Guidance notes on the UK Regulations**

**First edition**

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**dti**

Department of Trade and Industry

This guide is intended to assist manufacturers of equipment for use outdoors to understand the effect of the Regulations. It is not an authoritative interpretation of the Regulations, which is a matter for the Courts.

The guide seeks to explain the requirements of the Regulations in general terms and does not attempt to address detailed issues. You should refer to the Regulations themselves (SI 2001/1701) for a full statement of the requirements.

# Contents

	<b>Page</b>
The Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001 : The law in brief	2
Free movement of goods	3
General duties of manufacturers and others	4
The Noise Emission in the Environment by Equipment for use Outdoors Directive	4
Conformity assessment	5
Free circulation	11
Safeguard procedure	11
Enforcement	11
Repeal of Directives and their implementing Regulations	12
Availability of texts of Standards	13
Availability of texts of the Directive and Regulations	13
Contact points for further information	14
Annex A: EC Declaration of Conformity	15
Annex B: Models of the CE marking of conformity and of the indication of the guaranteed sound power level	16
Annex C: Internal Control of Production	17
Annex D: Internal Control of Production with assessment of technical documentation and periodical checking	18
Annex E: Unit Verification	21
Annex F: Full Quality Assurance	23
Annex G: Conformity Assessment Procedures (Diagram)	26

# THE NOISE EMISSION IN THE ENVIRONMENT BY EQUIPMENT FOR USE OUTDOORS REGULATIONS 2001 : THE LAW IN BRIEF

**The EC Noise emission in the environment by equipment for use outdoors Directive** was adopted by the European Parliament and the Council on 3 July 2000 as Directive 2000/14/EC. The Directive arises from the European Community's (EC) programme for the elimination of technical barriers to trade and is formulated under the 'Global Approach'. Its purpose is to harmonise national laws of member States regarding noise emission limits and labelling requirements at the manufacturing stage.

The Directive was implemented into UK law by The Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001 (SI 2001/1701) made under the European Communities Act 1972.

From **3 July 2001** until **2 January 2002** manufacturers or their authorised representatives based in the European Community of equipment for use outdoors have the choice of complying with the Regulations or continuing to comply with existing national legislation.

From **3 January 2002** all equipment for use outdoors within the scope of the Regulations placed on the market or put into service in the UK must comply with the Regulations.

Failure to comply with the Regulations will mean that these products may be prohibited from being placed on the Community\* market, or withdrawn if already placed on the market after 3 January 2002.

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\* There are fifteen members of the Community - Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK.

# FREE MOVEMENT OF GOODS

The free movement of goods lies at the heart of achieving an open market for business in Europe.

The Council Resolution of 1989 on the Global Approach to certification and testing states the following guiding principles for Community policy on conformity assessment:

- ❑ A consistent approach is developed in Community legislation by devising modules for the various phases of conformity assessment procedures, and by laying down criteria for the use of these procedures, for the designation of bodies operating these procedures, and for the use of the CE marking.
- ❑ The use of European standards relating to quality assurance (EN ISO 9000 series), and to the requirements to be fulfilled by conformity assessment bodies operating quality assurance (EN 45000 series) is generalised.
- ❑ Setting up of accreditation systems and the use of intercomparison techniques are promoted in member States and at Community level.
- ❑ Mutual recognition agreements concerning testing and certification in the non-regulatory sphere are promoted.
- ❑ The differences of existing quality infrastructures (such as calibration and metrology systems, testing laboratories, certification and inspection bodies, and accreditation bodies) between member States and between industrial sectors are minimised by programmes.
- ❑ International trade between the Community and third countries is promoted by means of mutual recognition agreements, co-operation and technical assistance programmes.

Directive 2000/14/EC on Noise emission in the environment by equipment for use outdoors is considered one of these 'Global Approach' Directives.

# GENERAL DUTIES OF MANUFACTURERS AND OTHERS

Under the Regulations, the onus to comply lies with the manufacturer or his authorised representative established in the Community. Where neither the manufacturer nor his authorised representative is established in the Community, the obligations of the Regulations shall apply to any person placing the equipment on the market or putting it into service in the Community.

'Placed on the market' is generally regarded as the initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community. Making available can be either for payment or free of charge. This is considered to have taken place when a product is transferred from the stage of manufacture to the retailer. Therefore, retailers will not be required to scrap or return old stocks of equipment supplied before 3 January 2002 as this equipment does not have to be brought into conformity with the Regulations. However, retailers should retain invoices for the equipment as proof of delivery date in case they are challenged by the enforcement authority.

Manufacturers holding old stocks of equipment in their warehouses after 3 January 2002 will be required to bring this equipment into conformity with the Regulations before it can be placed on the market or put into service.

Retailers are not usually affected by the Regulations unless they are also the manufacturer or are responsible for importing the equipment and placing it for the first time on the Community Market.

Users are not affected by the Regulations unless they are purchasing and importing equipment from outside of the Community for their own use. The obligations of the Regulations will then apply to them as they are putting the equipment into service for the first time within the Community.

## THE NOISE EMISSION IN THE ENVIRONMENT BY EQUIPMENT FOR USE OUTDOORS REGULATIONS 2001 (SI 2001/1701)

**Entry into force of the UK Regulations:** 3 July 2001

**Transitional arrangements:** there is a transitional period from 3 July 2001 until 2 January 2002 during which time manufacturers will have the option of complying with the new regime or the national legislation in force on 3 July 2000 in the member State in which the equipment is placed on the market.

**Mandatory application of the UK Regulations:** 3 January 2002

**Coverage:** the Regulations apply to 57 types of equipment for use outdoors ranging from construction machinery to lawnmowers which require noise emission

measurements to be taken and to fix labels showing the “guaranteed” noise levels of each machine. In addition, the Regulations set noise limits for 22 of the 57 categories which are laid down in two stages. The Regulations only cover equipment that is first placed on the market or put into service as an entire unit suitable for the intended use.

**Excluded products:** the Regulations **do not** apply specifically to:

- Non-powered attachments that are separately placed on the market, except for hand-held concrete-breakers and picks and for hydraulic hammers.
- All equipment primarily intended for the transport of goods or persons by road or rail or by air or on waterways.
- Equipment specially designed and constructed for military and police purposes and for emergency services.

### **Second-hand equipment:**

Second-hand equipment and equipment already in use within the Community is not covered by the Regulations. However, the Regulations apply to second-hand equipment used in any country or territory outside the Community when it is imported for the first time into the Community.

### **Definitions of Noise terms:**

**“sound power level  $L_{WA}$ ”** means the A-weighted sound power level in dB in relation to 1 pW as defined in EN ISO 3744:1995 and EN ISO 3746:1995.

**“measured sound power level”** means a sound power level as determined from measurements as laid down in Schedule 6 of the Regulations; measured values may be determined either from a single machine representative for the type of equipment or from the average of a number of machines.

**“guaranteed sound power level”** means a sound power level determined in accordance with the requirements laid down in Schedule 6 of the Regulations which includes the uncertainties due to production variation and measurement procedures and where the manufacturer, or his authorised representative established in the Community, confirms that according to the technical instruments applied and referred to in the technical documentation it is not exceeded.

## **CONFORMITY ASSESSMENT**

Equipment will be subject to conformity assessment based on EC Decision 93/465/EEC of 22 July 1993 which set down a framework of conformity assessment ‘modules’ intended for use in New and Global Approach Directives (although the procedure for the internal control of production with assessment of technical documentation and periodical checking procedure is a divergence from Module

Aa in the Decision). Manufacturers will be given a choice of 'modules' dependant on whether the equipment is in the group subject to noise limits or noise marking only. A flowchart showing the conformity assessment procedures for the purposes of the Regulations appears in Annex G.

### **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 established in the Community, 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 D of this publication,
- or the unit verification procedure referred to in Annex E,
- or the full quality assurance procedure referred to in Annex F.

All three of the above will require the involvement of 'Notified Bodies'.

### **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 his authorised representative established in the Community, shall subject each type of equipment to:

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

The procedure under Annex C will not require the involvement of 'Notified Bodies'.

### **Equipment subject to noise limits and noise marking:**

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

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

### **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 ( $\geq 400$  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.*

## 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>(1)</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 $89 + 11 \lg P$	105 106 $86 + 11 \lg P$
Tracked dozers, tracked loaders, tracked excavator-loaders	$P \leq 55$ $P > 55$	106 $87 + 11 \lg P$	103 $84 + 11 \lg P$
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          $85 + 11 \lg P$	101          $82 + 11 \lg P$
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 $92 + 11 \lg m$ $94 + 11 \lg m$
Tower cranes		$98 + \lg P$	$96 + \lg P$
Welding and power generators	$P_{el} \leq 2$ $2 < P_{el} \leq 10$ $P_{el} > 10$	$97 + \lg P_{el}$ $98 + \lg P_{el}$ $97 + \lg P_{el}$	$95 + \lg P_{el}$ $96 + \lg P_{el}$ $95 + \lg P_{el}$
Compressors	$P \leq 15$ $P > 15$	99 $97 + 2 \lg P$	97 $95 + 2 \lg P$
Lawnmowers, lawn trimmers/lawn edge trimmers	$L \leq 50$ $50 < L \leq 70$ $70 < L \leq 120$ $L > 120$	96 100 100 105	$94^{(2)}$ 98 $98^{(2)}$ $103^{(2)}$

<sup>(1)</sup>  $P_{el}$  for welding generators: conventional welding current multiplied by the conventional load voltage for the lowest value of the duty factor given by the manufacturer

$P_{el}$  for power generators: prime power according to ISO 8528-1:1993, clause 13.3.2

<sup>(2)</sup> Indicative figures only.

The permissible sound power level shall be rounded to the nearest whole number (less than 0.5 use lower number; greater than or equal to 0.5 use higher number)

Stage I limits are applicable from 3 January 2002. During the 6 months transition period prior to that date Stage I limits are optional. Limits are reduced in Stage II which commences 3 January 2006.

Indicative figures for lawnmowers and lawn trimmers/lawn edge trimmers have been entered for Stage II. The Stage II limits for this equipment will be decided by 3 July 2002, when the European Commission will produce a report concerning whether and to what extent technical progress allows a reduction to the indicative targets. If the Commission fails to produce a report or an amendment to the Directive has not been made, the Stage I limits continue to apply in the case of lawnmowers and lawn trimmers/lawn edge trimmers only.

#### **Noise test methods:**

Methods of measurement of airborne noise to be used for the determination of the sound power levels are given in Schedule 6 of the Regulations. Schedule 6 may be amended in the future to adapt it to technical progress, in particular to include references to the relevant European standards. However, any such amendment shall not have any direct impact on the measured sound power level of the equipment subject to limits. Manufacturers should adhere to the versions of standards given in Schedule 6. Subsequent versions must not be used until they are included in Schedule 6 by amendment.

#### **Technical documentation:**

All conformity assessment procedures require the production of technical documentation by the manufacturer or his authorised representative established in the Community.

#### **Notified Bodies:**

For the purposes of the Regulations, a Notified Body is a body which either has been appointed by the Secretary of State for Trade and Industry as a United Kingdom Notified Body, or appointed by a member State in the Community other than the United Kingdom, to carry out one or more of the conformity assessment procedures referred to above. In the case of United Kingdom Notified Bodies, appointments will be made following assessment by the United Kingdom Accreditation Service (UKAS) in accordance with the DTI guidelines for appointment (ref. URN 01/753). Copies of the guidelines are available from the DTI contact on page 14. A list of UK Notified Bodies is available from the STRD website or the DTI on request.

The manufacturer or his authorised representative established in the Community may use the services of Notified Bodies based in any of the 15 member States.

#### **CE Marking:**

Once conformity assessment has been completed, and if the equipment subsequently complies with the provisions of the Regulations and any other applicable Regulations, the manufacturer will be required to affix the CE marking together with the indication of the guaranteed sound power level in a visible, legible and indelible form to each item of equipment (see Annex B for details).

## **Guaranteed Sound Power Level:**

The Guaranteed Sound Power level includes the measured sound power level of the product and any uncertainties due to production and measurement variations (see definition on page 5). The manufacturer is responsible for determining the level of uncertainty and must include it in the calculation of the Guaranteed Sound Power Level.

Products subject to limit values will have an upper limit for the Guaranteed Sound Power Level, as determined by the noise limit table on page 8 of this guide (Schedule 3 of the Regulations). Guaranteed Sound Power Levels must be lower or equal to the noise limit value. Products subject to noise marking only are not subject to an upper limit.

However, in all cases the Guaranteed Sound Power Level, as indicated on the product, must not be exceeded.

## **EC Declaration of Conformity:**

In order to certify that an item of equipment is in conformity with the provisions of the Regulations, the manufacturer shall draw up an EC declaration of conformity for each type of equipment manufactured. Minimum contents of the EC declaration of conformity are reproduced at Annex A.

A member State may require that the declaration of conformity be drawn up in or translated into the official Community language or languages determined by the member State when equipment is placed on the market or put into service in its territory. For equipment placed on the market or put into service in the UK, the declaration of conformity must be in English.

The EC declaration of conformity may be combined with the declaration of conformity required under other Directives, for example, the Machinery Directive.

The manufacturer or his authorised representative established in the Community shall ensure that:

- the EC declaration of conformity shall accompany the product;
- they keep a copy of the EC declaration of conformity for 10 years from the date of when the last piece of equipment was manufactured;
- they send a copy of the EC declaration of conformity for each type of equipment to the responsible authority of the member State where he places on the market or puts into service the equipment. In the UK this must be sent to:

DTI  
PO Box 1302  
Bristol BS99 2GB

and;

- they also send a copy of the EC declaration of conformity for each type of equipment to the European Commission contact below:

FAO The Secretary General  
(DG Environment - Noise Directive 2000/14/EC)  
200 Rue de la Loi  
B-1048 Brussels  
Belgium

## **FREE CIRCULATION**

Under European Community law - as set out in the Noise emission in the environment by equipment for use outdoors Directive - member States must not prohibit, restrict or impede the placing on the market or putting into service in their territory equipment which complies with the provisions of this Directive. Furthermore, member States are to presume that equipment bearing the CE marking together with the indication of the guaranteed sound power level, and accompanied by an EC declaration of conformity, meets the provisions of the Directive.

## **SAFEGUARD PROCEDURE**

Member States are required to take all appropriate measures to withdraw from the Community market, or to prohibit and restrict the supply of products where limit values are exceeded or any other non-compliance with the provisions of the Directive continues. They must then inform immediately the European Commission and other member States of its action and give reasons. The Commission must consult the parties concerned as soon as possible and inform immediately all member States whether it find the measures justified or unjustified.

## **ENFORCEMENT**

The Vehicle Certification Agency (VCA), an Executive Agency of the Department of the Environment, Transport and the Regions, is responsible for the enforcement of the UK Regulations. The Secretary of State for Trade and Industry may also enforce the Regulations.

To ensure that only compliant equipment is being placed on the market, the VCA will carry out proactive surveillance as well as investigating complaints from industry and other stakeholders, etc. to establish whether there are justifiable grounds for taking enforcement action. In response to complaints, the VCA will seek evidence that the Regulations have been breached and consider what action should be taken.

The VCA are seeking to work with manufacturers to help them comply with the Regulations properly as well as taking enforcement action against suppliers of non-compliant equipment. Suppliers of equipment wishing to seek assurance that their products meet the requirements of the 2001 Regulations can make enquiries to the VCA (contact given on page 14). Clearly it is in the supplier's own interest to discuss at an early stage any problems they may have in applying the Regulations to their products.

# REPEAL OF DIRECTIVES AND THEIR IMPLEMENTING REGULATIONS

The following Directives will be repealed with effect 3 January 2002:

- Council Directive **79/113/EEC** of 19 December 1978 on the approximation of laws of the member States relating to the determination of the noise emission of **construction plant and equipment** (as amended);
- Council Directive **84/532/EEC** of 17 September 1984 on the approximation of laws of the member States relating to common provisions for **construction plant and equipment** (as amended);
- Council Directive **84/533/EEC** of 17 September 1984 on the approximation of laws of the member States relating to the permissible sound power level of **compressors**;
- Council Directive **84/534/EEC** of 17 September 1984 on the approximation of laws of the member States relating to the permissible sound power level of **tower cranes**;
- Council Directive **84/535/EEC** of 17 September 1984 on the approximation of laws of the member States relating to the permissible sound power level of **welding generators**;
- Council Directive **84/536/EEC** of 17 September 1984 on the approximation of laws of the member States relating to the permissible sound power level of **power generators**;
- Council Directive **84/537/EEC** of 17 September 1984 on the approximation of laws of the member States relating to the permissible sound power level of powered **hand-held concrete-breakers and picks**;
- Council Directive **84/538/EEC** of 17 September 1984 on the approximation of laws of the member States relating to the permissible sound power level of **lawnmowers**;
- Council Directive **86/662/EEC** of 22 December 1986 on the limitation of noise emitted by **hydraulic excavators, rope-operated excavators, dozers, loaders and excavator-loaders**.

The respective 2001 Regulations revoke, with effect 3 January 2002, the following Regulations which implemented these Directives in Great Britain and Northern Ireland:

- The Construction Plant and Equipment (Harmonization of Noise Emission Standards) Regulations 1985 (SI 1985/1968 as amended);
- The Construction Plant and Equipment (Harmonisation of Noise Emission Standards) Regulations 1988 (SI 1988/361 as amended);
- The Construction Plant and Equipment (Noise Emission) Regulations (Northern Ireland) 1987 (SR 1987 No 328 as amended);
- The Lawnmowers (Harmonization of Noise Emission Standards) Regulations 1992 (SI 1992/168 as amended).

Type-examination certificates issued under the above legislation will be invalid from 3 January 2002. This equipment will need to be certified under Directive 2000/14/EC before it can continue to be placed on the EU market. Type-examination certificates issued and measurements of equipment carried out under the above legislation may be used in drawing up the technical documentation provided for in the conformity assessment procedures described in Annexes C, D, E and F.

## AVAILABILITY OF TEXTS OF STANDARDS

These may be obtained from BSI Sales (contact given on page 14).

**Please note that the DTI does not supply copies of the Standards.**

## AVAILABILITY OF THE TEXTS OF THE DIRECTIVE AND REGULATIONS

The complete text of the Directive 2000/14/EC has been published in the *Official Journal of the European Communities* (No. L162 of 03.07.00). Copies of the text are generally available from European Information Centres and European Documentation Centres located throughout the United Kingdom, who may provide them for a modest charge.

The Regulations are available from the Stationery Office (contact given on page 14).

## ADDITIONAL COPIES OF THIS PUBLICATION

Additional copies or bulk supplies of the publication are available free of charge from the DTI Publications Orderline

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Fax: 0870 1502 333  
Minicom: 0870 1502 100  
E-mail: [dtipubs@eclogistics.co.uk](mailto:dtipubs@eclogistics.co.uk)  
Website: <http://www.dti.gov.uk/publications>

It is also downloadable in Adobe Acrobat format from our website at <http://www.dti.gov.uk/strd>

# CONTACT POINTS

## Policy relating to the Regulations:

Fran Buckle  
Department of Trade & Industry  
322 Red Zone  
151 Buckingham Palace Road  
London SW1W 9SS

Tel: 020 7215 1977  
Fax: 020 7215 1529  
Web Site: <http://www.dti.gov.uk/strd/>

## Policy relating to the Directive:

Directorate-General Environment  
European Commission  
Rue de la Loi 200  
B-1049 Brussels  
Belgium

Web Site: <http://europa.eu.int/comm/environment/noise/home.htm>

## Enforcement:

Rob Wollacott  
Vehicle Certification Agency  
1 The Eastgate Office Centre  
Eastgate Road  
Bristol BS5 6XX

Tel: 0117 952 4160  
Fax: 0117 952 4146  
Web Site: <http://www.vca.gov.uk>

## Standards:

BSI Standards  
389 Chiswick High Road  
Chiswick  
London W4 4AL

Tel: 020 8996 9000  
Fax: 020 8996 7400  
Web Site: <http://www.bsi-global.com>

## The Stationery Office:

The Stationery Office  
*(Mail, telephone and fax orders only)*  
PO Box 29  
Norwich NR3 1GN

Tel: 0870 600 5522  
Fax: 0870 600 5533  
E-mail: [book.orders@theso.co.uk](mailto:book.orders@theso.co.uk)  
Web Site: <http://www.clicktso.com>

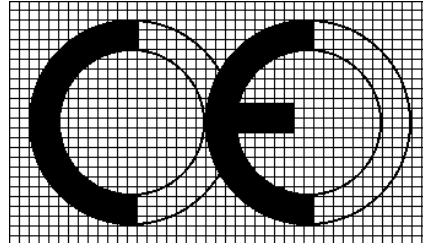
## EC DECLARATION OF CONFORMITY

The EC declaration of conformity must contain the following particulars:

- name and address of the manufacturer or his authorised representative established in the Community;
- 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 this Directive;
- the declaration that the equipment conforms to the requirements of this Directive;
- where appropriate, the declaration(s) of conformity and references of the other Community Directives applied;
- the place and date of the declaration;
- particulars of the signatory authorised to sign the legally binding declaration for the manufacturer or his authorised representative established in the Community.

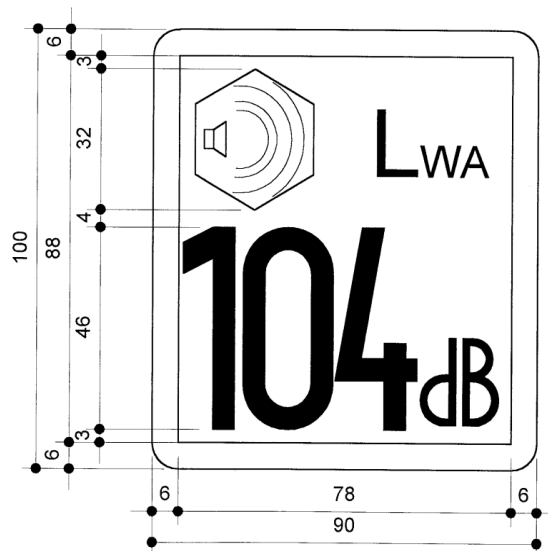
## MODELS OF THE CE MARKING OF CONFORMITY AND OF THE INDICATION OF THE GUARANTEED SOUND POWER LEVEL

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



If the CE 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 CE 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.

## INTERNAL CONTROL OF PRODUCTION

1. This Annex describes the procedure whereby the manufacturer, or his authorised representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the equipment concerned satisfies the requirements of this Directive. The manufacturer, or his authorised representative established in the Community, must affix the CE marking of conformity and the indication of the guaranteed sound power level as required in Article 11 of this Directive to each equipment and draw up a written EC declaration of conformity as required in Article 8 of this Directive.
2. The manufacturer, or his authorised representative established in the Community, 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 his authorised representative established in the Community, 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 EC declaration of conformity.
3. The technical documentation must enable the conformity of the equipment with the requirements of this Directive to be assessed. It must contain at least the following information:
  - name and address of the manufacturer or his authorised representative established in the Community;
  - 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 this Directive;
  - the technical report of noise measurements carried out in accordance with the provisions of this Directive;
  - 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 this Directive.

## INTERNAL CONTROL OF PRODUCTION WITH ASSESSMENT OF TECHNICAL DOCUMENTATION AND PERIODICAL CHECKING

1. This Annex describes the procedure whereby the manufacturer, or his authorised representative established in the Community, who carries out the obligations laid down in points 2, 5 and 6 ensures and declares that the equipment concerned satisfies the requirements of this Directive. The manufacturer, or his authorised representative established in the Community, must affix the CE marking of conformity and the indication of the guaranteed sound power level as required in Article 11 of this Directive to each equipment and draw up a written EC declaration of conformity as required in Article 8 of this Directive.
2. The manufacturer, or his authorised representative established in the Community, 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 his authorised representative established in the Community, 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 EC declaration of conformity.
3. The technical documentation must enable the conformity of the equipment with the requirements of this Directive to be assessed. It must contain at least the following information:
  - name and address of the manufacturer or his authorised representative established in the Community;
  - 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 this Directive;
  - the technical report of noise measurements carried out in accordance with the provisions of this Directive;
  - 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 this Directive.
5. *Evaluation by the Notified Body prior to placing on the market.*

The manufacturer, or his authorised representative established in the Community, shall present a copy of his technical documentation to a Notified Body of his choice before the first item of equipment is placed on the market or put into service.

If there are doubts about the plausibility of the technical documentation the Notified Body shall inform accordingly the manufacturer or his authorised representative established in the Community, and, if need be, carry out, or have carried out, modifications of the technical documentation, or possibly, tests deemed necessary.

After the Notified Body has issued a report confirming that the technical documentation satisfies the provisions of this Directive, the manufacturer or his authorised representative established within the Community may affix the CE marking to the equipment and issue an EC declaration of conformity in accordance with Articles 11 and 8 of this Directive, for which he will hold complete responsibility.

6. *Evaluation by the Notified Body during production.*

The manufacturer, or his authorised representative established in the Community, shall further involve the Notified Body in the production phase according to one of the following procedures to be chosen by the manufacturer or his authorised representative established within the community:

- 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 this directive; in particular the Notified Body shall concentrate on:
  - the correct and complete marking of the equipment according to Article 11 of this Directive,
  - issuing of the EC declaration of conformity according to Article 8 of this Directive,
  - 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.

The manufacturer, or his authorised representative established in the Community, 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.

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 this Directive for the relevant type of equipment.

- 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 this Directive, or equivalent tests, must be carried out to check the conformity of the product with the relevant requirements of this Directive. The product checking must include the following aspects:
  - the correct and complete marking of the equipment according to Article 11 of this Directive,
  - issuing of the EC declaration of conformity according to Article 8 of this Directive.

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.

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 his authorised representative established in the Community.

In those cases where equipment checked does not conform to the provisions of this Directive, the Notified Body must inform the notifying member State.

## UNIT VERIFICATION

- 1 This Annex describes the procedure whereby the manufacturer, or his authorised representative established in the Community, ensures and declares that the equipment which has been issued with the certificate referred to in point 4 conforms to the requirements of this Directive. The manufacturer, or his authorised representative established in the Community, must affix the CE marking supplemented by the information as required in Article 11 of this Directive to the equipment and draw up the EC declaration of conformity referred to in Article 8 of this Directive.
- 2 The application for a unit verification must be lodged by the manufacturer or his authorised representative established in the Community with a Notified Body chosen by him.

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 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 this Directive.
- 3 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 this Directive, the noise tests will be carried out
    - in accordance with this Directive, carry out or have carried out the necessary noise tests.

- 4 Where the equipment meets the provisions of this Directive, the Notified Body must issue a certificate of conformity to the applicant as described in Annex X of this Directive.

If the Notified Body refuses to issue a certificate of conformity, it must state the detailed grounds for the refusal.

- 5 The manufacturer, or his authorised representative established in the Community, 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 market.

## 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 this Directive. The manufacturer, or his authorised representative established in the Community, must affix the CE marking supplemented by the information as required in Article 11 of this Directive to each product and draw up the written EC declaration of conformity referred to in Article 8 of this Directive.
- 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.
- 3 *Quality assurance system*
  - 3.1 The manufacturer must lodge an application for assessment of his quality assurance system with a Notified Body of his choice.

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 his authorised representative established in the Community
  - 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 this Directive
  - the technical report of noise measurements carried out in accordance with the provisions of this Directive
  - 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 EC declaration of conformity.
- the documentation concerning the quality assurance system.

- 3.2 The quality assurance system must ensure compliance of the product with the requirements of the Directives that apply to it.

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.

- 3.3 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.

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.

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.

The decision must be notified to the manufacturer. The notification must contain the conclusion of the examination and the reasoned assessment decision.

- 3.4 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.

The manufacturer or his authorised representative established within the Community shall keep the Notified Body that has approved the quality assurance system informed of any intended updating of the quality assurance system.

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.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

#### 4 *Surveillance under the responsibility of the Notified Body*

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

4.2 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.,
- 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.

4.3 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.

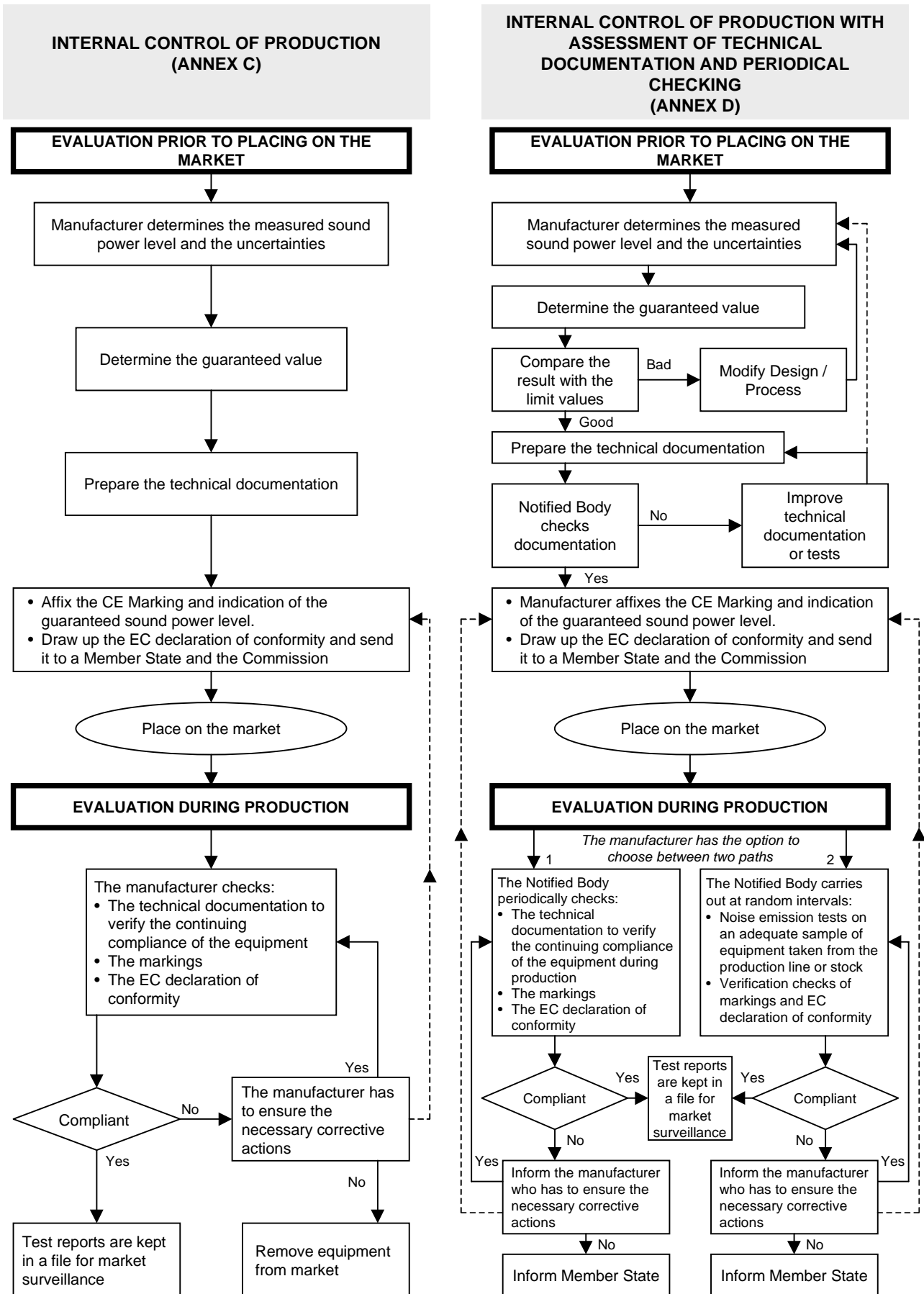
4.4 Additionally the Notified Body may pay unexpected visits to the manufacturer. During such visits the Notified Body may carry out, or cause to be carried out, tests to verify that the quality assurance system is functioning correctly, if necessary. The Notified Body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5 The manufacturer must, for a period ending at least 10 years after the last equipment has been manufactured, keep at the disposal of the national authorities:

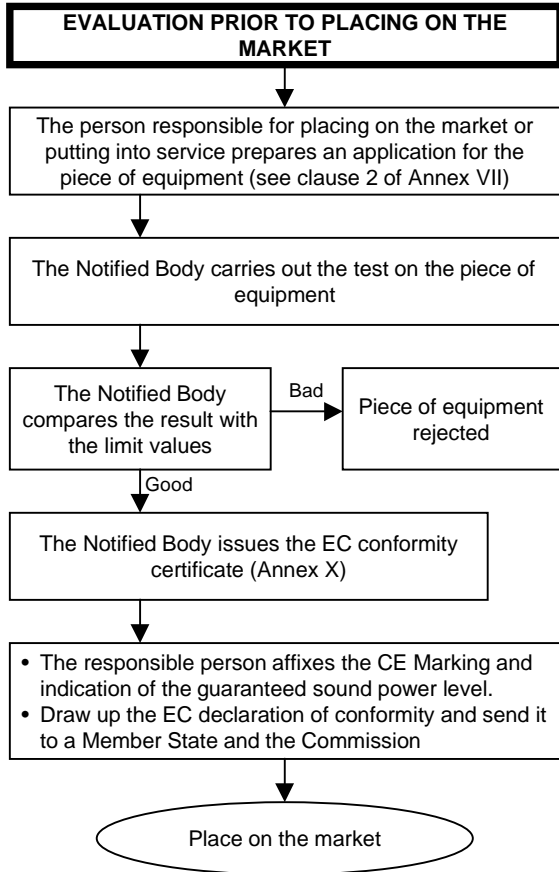
- the documentation referred to in the second indent of point 3.1 of this Annex;
- the updating referred to in the second paragraph of point 3.4;
- the decisions and reports from the Notified Body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.

6 Each Notified Body must give the other Notified Bodies the relevant information concerning the quality assurance system approvals issued and withdrawn.

# CONFORMITY ASSESSMENT PROCEDURES



### UNIT VERIFICATION (ANNEX E)



*Note: This module is used only for a single piece of equipment or for second hand equipment used in any country or territory outside the Community when it is imported for the first time into the Community*

### FULL QUALITY ASSURANCE (ANNEX F)

