PART II

Chapter 13

Instruments and Devices

1. Introduction

Optical, photographic, measuring, checking, medical and surgical instruments and devices are covered under chapter 90 of the EC's Common Customs Tariff (CCT) code. Other mechanical devices can be found in Chapter 84 of the CCT code. Customs duties range from 3.8% to 10%. All instruments and devices for use in civil aircraft enter the EC free of customs duties.

Due to the technical nature of these product groups, the EC recognises the danger of technical barriers to realisation of the Single European Market. Each Member State has its own arrangements for testing and certifying products. These national technical barriers are progressively being eliminated through EC legislation. Standards have already been issued for instruments particularly in the medical field and others are presently under discussion.

2. Non-automatic weighing instruments

As of 1st January 1993, non-automatic weighing instruments must comply with EC regulations. Non-automatic weighing instruments are classified into two categories:

- Category A: instruments which determine mass for commercial transactions;
  to calculate a toll, tariff, tax, penalty;
  when applying laws or regulations;
  to weigh patients in the practice of medicine;
  to make up medicines on prescription;
  to fix a price for direct sale to public.
- Category B: instruments used for any other purpose. e.g. domestic and industrial process control.

Non-automatic weighing machines must be submitted for EC-type examination to ensure that it satisfies EC standards. Approved products can then carry the CE mark.

Category A instruments must comply with essential requirements in the following areas:

- accuracy
- units of measurement
- design
- construction.

Standards to be followed are based on Recommendation No. 76 of the International Organisation of Legal Metrology (OIML).

For full details of the OIML recommendation contact OIML as detailed in Section 4.

Category B instruments need not meet essential requirements of that of Category A and do not have to carry the CE mark. However these instruments must carry the manufacturer's or EC seller's name or mark and indicate maximum capacity in a clearly visible, easily legible and indelible form. Information of

specific requirements of this EC legislation can be found in the EEC's Official Journal OJ L189 of 20 July 1990, ref. 90/384/EC.

3. Medical Instruments and Devices

A series of three directives regulating the safety and marketing of medical devices is being implemented throughout the EC. Legislation on active implantable medical devices was recently adopted by the EC and comes into effect on 1 January 1993. This legislation covers powered medical devices implanted in the human body such as heart pace-makers. Implantable medical devices sold within the EC must:

- safeguard the clinical condition and safety of patients, and not present any risks to others
- meet safety and efficacy requirements in their design, construction and materials used
- have been designed and manufactured subject to independent checks
- carry a CE mark; and provide instructions.

In order to show that products meet essential requirements manufacturers must either follow the EC declaration of conformity procedure, or

- follow EC type-examination procedure followed by either the EC notification procedure or the EC declaration of conformity to type procedure.

Please refer to Part I, Chapter 2 on product standardisation for descriptions of the above procedure.

Information on requirements upon active implantable devices can be found in the EC's Official Journal OJ L189 of 20 July 1990, ref. 90/385/EEC.

Legislation on medical devices, ranging from, for example, first aid bandages to CT scanners is expected to come into effect in the EC before late 1994. Requirements similar to medical implantable devices on safety, design, construction and efficacy is expected to be set out by this legislation.

Under this proposed legislation products are classified according to potential risk to consumer. The following classifications have been proposed:

CLASS I

Devices which do not enter into contact or interact with the body. The manufacturer alone is responsible for assessment of conformity to essential requirements and no third party verification is included.

CLASS II

Devices which are invasive or implantable or which interact with the body. Manufacturers must have products evaluated by a notified agency.

CLASS III

Devices which concern functions of vital organs. Products must be evaluated by a notified agency but will require more vigorous examination and more detailed information such as assessment of conformity based on clinical data.

Products to be included under these classifications are under discussion.

The third Directive in this product group covers medical devices, apparatus or systems to be used in-vitro for examination of substances derived from the human body. Drafting of this legislation has just begun and it is unlikely that it will take effect before 1996.

For more information contact the European Commission (DG III) as detailed in Part III.

4. Further Information and Contact Points

TRADE ASSOCIATIONS	TRADE FAIRS & EXHIBITION
1. ***European Committee of Weighing Instruments Manufacturers*** 36 Querue Hoche F-75008 Paris, France Tel: +33 1 45 61 18 51 Fax: +33 1 45 63 59 86 2. ***Coordination Committee of the Radiological and Electromedical Industries*** P.O. Box 701261 Stresemannallee 19 D-6000 Frankfurt am Main 70 Germany Tel: +49 696 302206 Fax: +49 696 302390	1. ***INTERKAMA Market for Innovations in Measurement and Automation*** Location: Dusseldorf, Germany Contact: Dusseldorfer Mesegesellschaft mbH NOWEA Postfach 32 02 03 D-4000 Dusseldorf 30 Germany Tel: +49 211 456001 Fax: +49 211 4560668 Frequency: Every two years in October Next fair - 1994 2. ***INTERHOSPITAL*** Location: Hanover, Germany Contact: Deutsche Messe AG Messegelande D-3000 Hanover 82 Germany Tel: +49 511 890 Fax: +49 511 8932626 Frequency: Every year in June

1. ***European Commission***
   200 Rue de la Loi
   1049 Brussels
   Belgium
   Tel: +32 2 299 1111

2. ***International Organisation of Legal Metrology (OIML)***
   11 Rue Turgot
   F-75009 Paris
   France
   Tel: +33 1 48 78 12 82
   Fax: +33 1 48 82 17 27

Product Example

Non-Automatic Weighing Instruments

Product Coverage

CCT NUMBER	PRODUCT DESCRIPTION
842310	Personal weighing machines (household scales, baby scales)
842320	Scales for continuous weighing of goods on conveyors
842330	Constant weight scales
842380	Other weighing machines

Customs Duties

CCT NUMBER	FULL	ACP	GSP	LDDC
842310	4.4%	0%	0%	0%
842320	4.4%	0%	0%	0%
842330	4.4%	0%	0%	0%
842380	4.4%	0%	0%	0%

Products and Standards

Non-automatic weighing instruments are divided into two product categories:

Class A:

Instruments which determine mass:

- for commercial transactions
- to calculate a toll, tariff, tax, bonus, penalty, renumeration or similar type of payment
- to weigh patients for monitoring, diagnosis or medical treatment
- to make up medicines on prescriptions in a pharmacy, or in analysis in medical or pharmaceutical laboratories
- to fix a price for direct sale to the public, or to make up pre packages.

Class B:

Instruments used for other purposes eg, domestic and industrial processing control.

Class B instruments are not subject to legislation and need not meet essential requirements. Class B instruments must however carry a manufacturer's mark or name, and indicate their maximum capacity in a clearly visible, easily legible and indelible form.

Class A instruments must meet the following essential requirements:

Metrological Requirements

1. Units of mass

The following units are permitted to be used in non-automatic weighing instruments:

- SI Units: kilogram, microgram, milligram, gram, tonne
- Imperial Units: pound, ounce, troy ounce
- Other non-SI Units: e.g. metric carat, in weighing precious stones.

2. Accuracy classes

The following accuracy classes have been defined:

- i - special
- ii - high
- iii - medium
- iv - ordinary.

The specifications of these classes have been set with corresponding verification scale intervals and minimum and maximum values.

Scale intervals have also been established. The actual scale interval (d) and the verification scale interval (e) shall be in the form:

- 1 x 10k 2 x 10k or 5 x 10k mass units
  (k being an integer or zero).

3. Classification and Accuracy

Instruments with one weighing range, instruments with multiple weighing ranges and multi interval instruments must be classified appropriately to a corresponding accuracy class given a specified verification scale interval. Non-automatic weighing instruments must not exceed the maximum permissible error of indication as shown in the table below.

Maximum Permissible Errors

LOAD				Maximum permissible error
Class I	**Class II**	**Class III**	**Class IIII**	
0≤m≤50000e	0≤m≤5000e	0≤m≤500e	0≤m≤50e	±0.5e
50000e<m≤2000000e	5000e<m≤20000e	500e<m≤2000e	50e<m≤200e	±1.0e
200000e<m	2000e<m≤1000000e	2000e<m≤10000e	200e<m100e	±1.5e

Weighing results of all instruments must be repeatable and shall be reproducible by the other indicating devices used and with other methods of balancing use. They should be sufficiently insensitive to changes in the position of the load on the load receptor and instruments should react to small variations in weight.

The following are general requirements for the design and construction of non-automatic weighing instruments:

1. Design and construction of the instrument shall be such that instruments will preserve their metrological qualities when properly used and installed, and when used in the environment for which they are intended. The value of the mass must be indicated.

2. When exposed to disturbances, electronic instruments shall not display the effects of significant faults, or shall automatically detect and indicate them.

3. Digital electronic devices shall always exercise adequate control of the correct operation of the measuring process, of the indicating facility and of all data storage and data transfer.

4. When external equipment is connected to an electronic instrument through an appropriate interface the metrological qualities of the instrument shall not be adversely influenced.

5. The instrument shall have no characteristics likely to facilitate fraudulent use. Components that may not be dismantled or adjusted by the user shall be secured against such action.

6. The indication of the weighing results and other weight values shall be accurate, unambiguous and non-misleading and the indicating device shall permit easy reading of the indication under normal conditions of use.

7. The following inscriptions must be indicated on the product:

- manufacturer's or importer's mark or name
- accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles
- maximum capacity in the form: MAX ...
- minimum capacity in the form: MIN ...
- verification scale interval in the form: E = H

Products which have met the essential requirements of the EC will be allowed to carry the CE Mark which must be clearly visible, easily legible and indelible.

Marketing and Distribution

The end users of weighing instruments are normally industrial users. It is better to appoint an EC representative or an agent who will promote products in the EC. The market is highly competitive: German and Japanese made products are well known for their technical features. Their products do well in industries where a high degree of accuracy is required. Products from the Far East, China and Taiwan cover the lower end of the market. In any case, with new legislation all products will have to meet the high quality standards now demanded throughout the EC.

Documentation

Aside from normal shipping and import documents, certificate of origin - Form A for GSP and LDDC countries, EUR 1 for ACP countries - must accompany consignments to benefit from reduced tariff or tariff free entry into the EC.

Other Information

Trade Association:

International Organisation of Legal Metrology
11 Rue Turgot
F-75009
Paris, France
Tel: +33 1 48 78 12 82
+33 1 42 85 27 11
Fax: +33 1 42 82 17 27

European Committee of Weighing Instruments Manufacturers
36 Avenue Hoche
F-75008
Paris, France
Tel: +33 1 45 61 18 51
Fax: +33 1 45 63 59 86

Trade Fairs:

INTERKAMA
Market Innovations in Measurement and Automation

Location:	Dusseldorf, Germany
Contact:	Dusseldorfer, Mesegesellschaft mbH NOWEA Postfach 32 02 03 D-4000 Dusseldorf 30 Germany Tel: +49 211 456001 Fax: +49 211 4560668
Frequency:	Every two years in October Next fair 1994

ACP Commonwealth Countries

ACP Commonwealth Countries

Entry Conditions:

Tariff free and quota free entry into the EC.

Rules of Origin:

Special rules of origin apply to all instruments and devices. In the majority of cases the rule of origin requires that the value of materials and components not coming from the ACP or EC countries must not be greater than 40% of the final price of the product.

Documentation:

Certificate of origin (EUR 1) must accompany products if the exporter is to benefit from tariff free entry into the EC. These forms can be obtained from the exporting country's national Customs and Excise office or Ministry of Trade.

GSP Commonwealth Countries

GSP Commonwealth Countries

Entry Conditions:

Tariff free and quota free entry into the EC.

Rules of Origin:

Special rules of origin apply to all instruments and devices. In the majority of cases the rule of origin requires that the value of materials and components not coming from the GSP country must not be greater than 40% of the final price of the product.

Documentation:

Certificate of origin (Form A) must accompany products if the exporter is to benefit from tariff free entry into the EC. These forms can be obtained from the exporting country's national Customs and Excise office or Ministry of Trade.

LDDC Commonwealth Countries

LDDC Commonwealth Countries

Entry Conditions:

Tariff free and quota free entry into the EC.

Rules of Origin:

Special rules of origin apply to all instruments and devices. In the majority of cases the rule of origin requires that the value of materials and components nc coming from the LDDC country must not be greater than 40% of the final price of the product.

Documentation:

Certificate of origin (Form A) must accompany products if the exporter is to benefit from tariff free entry into the EC. These forms can be obtained from the exporting country's national Customs and Excise office or Ministry of Trade.