



REPUBLIC OF CROATIA
STATE OFFICE FOR METROLOGY



Measuring Instruments Directive (2004/22/EC)

Implementation and Application

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REPUBLIC OF CROATIA
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Topics are:

- Basic principles of MID
- Measuring instruments
- Essential Requirements
- Responsibilities of the actors

Scope of 2004/22/EC (MID)

No barriers to the free movement of measuring instruments.
Measurements instrument shall provide a high level of protection.

Public - interest / - health / - safety / - order

Consumer protection

Fair trading

Levying of Taxes/duties

Environment protection

Measuring instruments concerned:

- Utility Meters (Clean Water, Gas, Heat, Electricity)
- Systems for Liquids other than Water
- Not *Non automatic weighing instruments*
- Automatic Weighing Instruments
- Taximeters
- Length- / capacity measures
- Dimensional Measuring Instruments
- Exhaust Gas Analysers

The basis for implementation

Subsidiarity requires that Member States remain responsible for their legal metrology control.

Optionality states that a Member States decide which instruments of the MID they want to regulate. *)

The MID has to be implemented into national legislation in accordance with the procedures of the individual Member States, leaving the national authorities the choice of form and means to be used.

The MID regulates only the procedures until placing on the market and surveillance of correct placing on the market (Article 18).

*) Regulations → <http://www.welmec.org/welmec/mid-information.html>

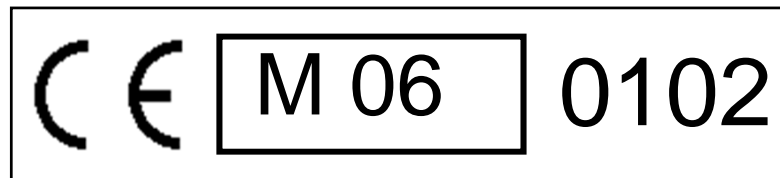
→ National Legislation may not act as a barrier of trade!

Regulated Instruments in % Member States

100 %			MI-005 Fuel Dispensers	(consum. Prot.)
97 %			MI-006 Automatic Weighing Instrum.	(fair trade)
97 %			MI-005 Systems on Road Tankers	(fair trade)
93 %			MI-005 Systems for Milk	(fair trade)
89 %			MI-007 Taximeters	(consum. prot.)
85 %			MI-010 Exhaust Gas Analysers	(environment)
82 %			MI-008 Material Measures: Length	(consum.prot.)
74 %			MI-008 Capacity measures	(taxes)
67 % - 70 %			MI-009 Dimensional Measuring Instruments	
Resid.	Com.	Industr.	Utility Meters:	(consum.prot.)
100%,	97 %	97 %	MI-003 Active Electrical Energy Meters	
93 %	, 83 %	, 74 %	MI-001 Clean cold Water Meters	
93 %	, 93 %	, 93 %	MI-002 Gas Meters	
89 %	, 85 %	, 85 %	MI-001 Clean warm Water Meters	
85 %	, 89 %	, 89 %	MI-002 Volume conversion devices	
82 %	, 78 %	, 78 %	MI-004 Heat Meters	

Legal Metrology Ticket valid in all involved states

CE marking and supplementary metrology marking, affixed under the responsibility of the manufacturer:



C E = Conformity to all applicable technical harmonisation Direct.

M = Conformity to Directive 2005/22/EC or 2009/42/EC

06 = Year of affixing the no. of the NB for placing on market

0102 = Identification no. of the notified body, responsible for the part of the conformity assessment procedure before 'placing on the market' and/or 'putting into use'

About responsibilities & conformity assessments

➤ Decision on Common framework for the marketing of products (768/2008/EC)

- Obligations of manufacturers, authorised representatives, importers, notified bodies, notifying authorities, member states
- Clarification of Safeguard procedures
- Harmonised conformity assessment procedures (Mod A – H1)

(all European Directives will be fitted to this decision in the next years, NAWID and MID until mid 2011)

A good introduction, but rather obsolete (Anno 2000):

„Guide to the Implementation of Directives Based on New Approach and Global Approach“ (so called „Blue Guide“)

Available from internet (e.g. google „blue guide new approach“)

Relevant new Regulations since 2008 (only EU/EEA states)

→ Regulation on laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State (764/2008/EC)

- Strengthen the functioning of the internal market by improving the free movement of goods
- Procedure for the application of a technical rules
- Requirements for product contact points and reporting obligations

→ Regulation on requirements for accreditation and market surveillance relating to the marketing of products (765/2008/EC)

- organisation and operation of accreditation bodies (accreditation of NB' is not mandatory)
- Community market surveillance framework
- Controls of products entering the Community market
- CE-marking, financing arrangement, penalties

Resume: National Regulations in legal metrology

Basis (for EU member states and if so EEA states):

- European Regulations (764/2008/EC, 765/2008/EC: EU/EEA)
- National Law on Legal Metrology - Verification Ordinance
- European Directives (have to be transposed into national legislation) - MID allows optionality
- Decision 768/2008: Common framework for the marketing of products (not yet mandatory, but will be implemented into all EU Directives)

Attention should be paid to further conditions:

- Directive 85/374/EEC concerning liability for defective products
- No interferences with other directives e.g. Directive 2006/123/EC on services in the internal market (only EU)
- OIML-Recommendations (www.oiml.org, members: States)
- WELMEC Guides (www.welmec.org, memb.: Nat. organisations)
- WTO agreements (www.wto.org, members: States)

MID regulates Placing on the market for putting into use

European Directives:
NAWID + MID

Manufacturer:
Conformity assessment
by Notified Bodies
→ CE + M marking
+ sealing metr. rel. parts

CE 06 0102 + M (NAWI)

CE M 06 0102 (MID)

→ **Placing on the market & Putting into use**

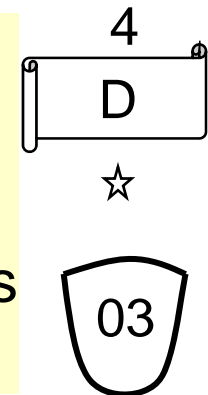
Old verification law (e.g. Germany):
(Two step procedure)

Manufacturer:
Pattern approval by PTB
→ PTB marking

18.10
02.10

→ **Placing on the market**

User: Initial verification/
by verification authority or
state approved test institute
→ Sealing of metr. rel. parts
+ verification mark



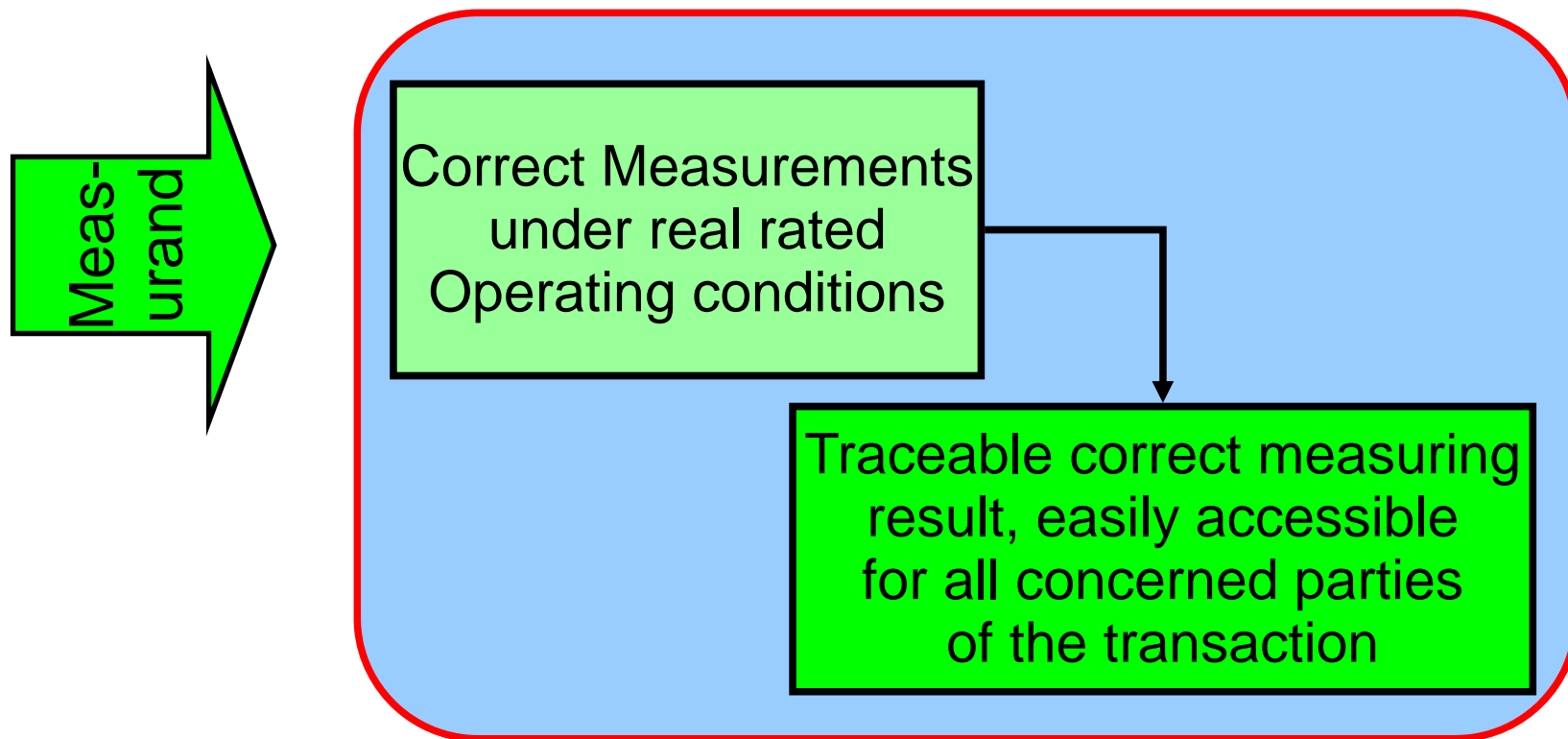
→ **Putting into use**

Only complete marked measuring instruments may be used!

Measurements under legal control covered by MID

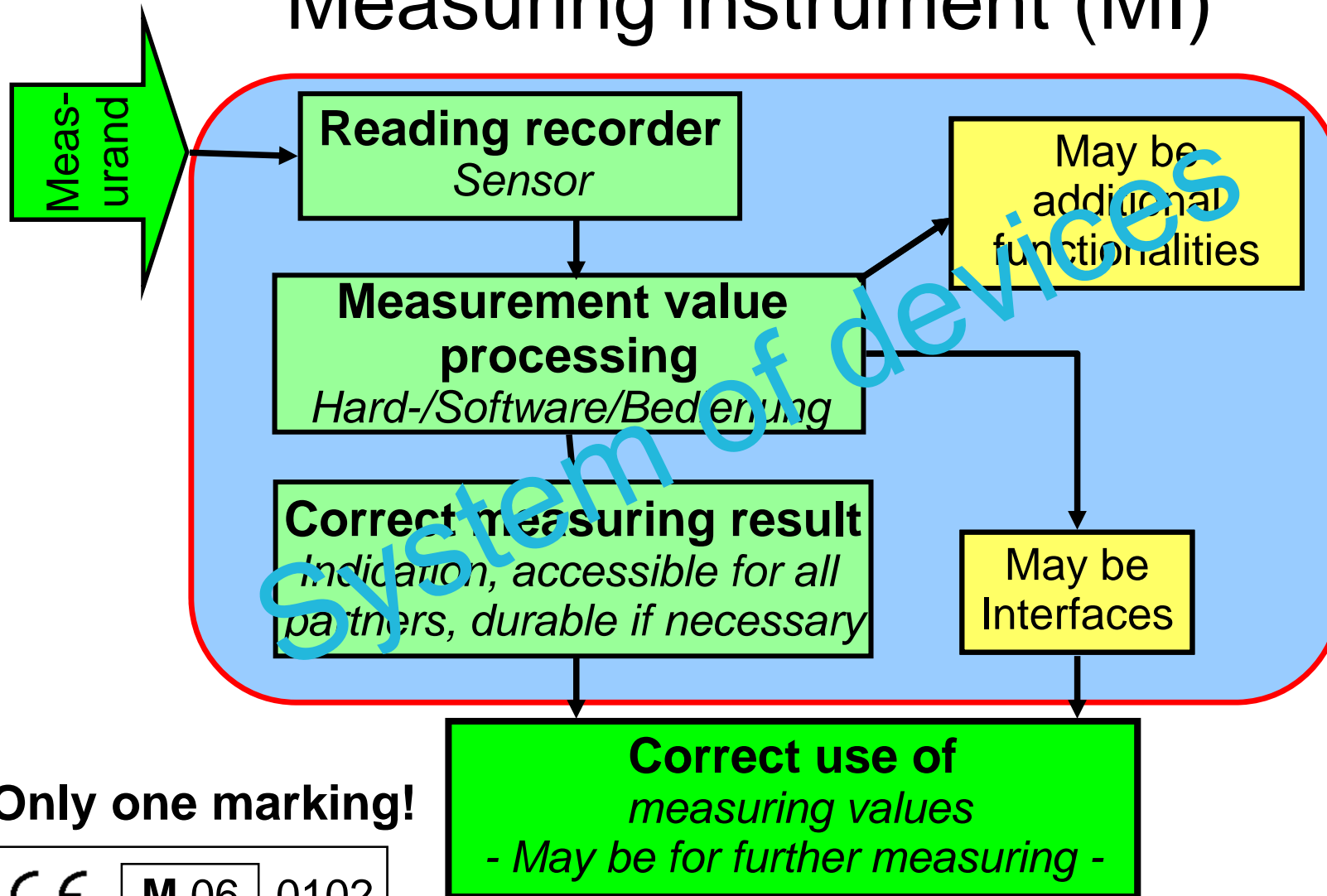
(Relevant objects - responsibilities of the involved actors)

Object: Legally controlled measurements with Measuring Instruments (MI)



Measuring instrument: Device or System

Measuring instrument (MI)



Only one marking!

CE M 06 0102

Sub-assemblies with MID conformity marking

Sub-assemblies are

- per se no measuring instruments (MI's)
- but functional devices **with their own MID-requirements**
- devices with their own MID-marking, type plate, operation manual
- make up a MI together with compatible sub-assemblies or MI's

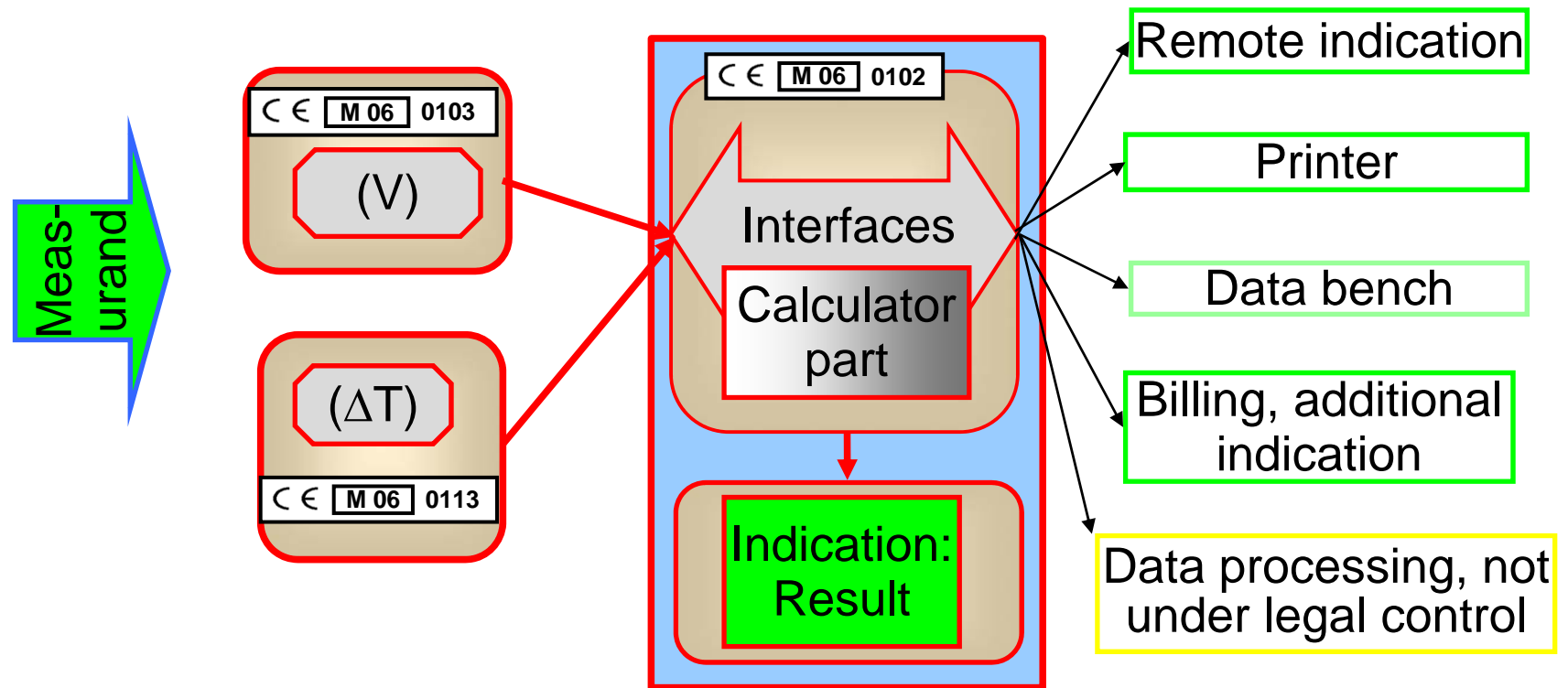
Difference between parts of a MI and MID-sub-assemblies:

Parts are combined by the manufacturer in his own responsibility to a MID-marked MI, for placing on the market / putting into use.

MID-marked sub-assemblies are combined by the user in his own responsibility due to the compatibility information in the user manual to a MI. If it is necessary to adjust metrological relevant parameters before putting into use, a breaking of a seal and a national control is necessary.

MID: Sub-assemblies = Parts conform to the MID

A Heat Meters (MI-004) may be one MI with one MID-CE- mark or consist of 3 MID-CE-marked sub-assemblies
(Flow sensor + Temp. sensor pair + Calculator)



MID-sub-assemblies are also: **Taximeter, Volume conv. devices**

General essential Requirements: MID, Annex I

1. Allowable Errors:

Under rated operating conditions (climate: different limits for upper and lower temperature; mechanical environment classes M1 to M3, electromagnetic classes E1 bis E3, power supply, Humidity etc.) MPE's for placing on the market are usually smaller than the allowed MPE's for instruments in use.

2. - 4. Reproducibility, Repeatability, Sensivity

→ specific instrument requirements (MI-0xx)

5. Durability:

Metrological characteristics (e.g. Max. perm. Errors) shall be stable over a period of time estimated by the manufacturer, when the MI is used according to the manufacturers instructions

6. Reliability:

Defects of the MI, which are not obvious for the user, shall not lead to inaccurate measuring results

Essential Requirements: MID, Annex I

7. Suitability:

Prevention of fraudulent use / unintentional misuse. Suitable under the specified conditions of use. No unreasonable high demands to the user. Metrological relevant software shall be identifiable and not be influenced by associated software. MI must allow the control of the measuring task after putting into use, the test procedure shall be described in the operation manual, special equipment or software shall be part of the MI.

8. Protection against corruption:

Connected devices shall not influence metrological characteristics. Securing of all metrological relevant parts (Hard- and Software). Evidence of an intervention shall be available for a reasonable period of time. Easy identification of the software by the MI. Protection of the software and if necessary of stored or transmitted data or parameters against corruption.

Essential Requirements: MID, Annex I

9. Information to be born by and to accompany the Instrument:

Manufacturers name or sign. Accuracy, measuring range etc..

Conditions of use, operating conditions. Identity marking.

Interfaces and compatibility to sub assemblies. Faulty operation based on incomplete information devolve on the manufacturer!

10. Indication of result:

Metrologically controlled Indication accessible for all involved parties. Non controlled records must be marked as that. For utility measurements there must be always an metrologically controlled indication for the customer. This must display the measurement result that serves as the basis for the price!

11. Further processing of data to conclude the trading transaction:

Durable measurement result accessible for all involved parties after end of measurement with identification of the measurement, when it is not repeatable and took place in absence of parties.

Instrument specific annexes MI-XXX

- shall regulate only those conditions necessary for „correct“ measurements – no technical realisations,
- shall provide together with annex I basics for technical realisations and harmonised standards as state of the art.

Regulations as far as necessary for the purpose of use:

- Specific rated operating conditions
- Maximum permissible errors under rated operating conditions
- Indication of the result
- Allowed conformity assessment procedures
- Requirements for putting into use (utility meters)
- Concretions of essential requirements, e.g. climatic classes, accuracy classes, indication, permissible effects of disturbances suitability, durability

Helpful tools for manufacturers and NB's

- **Harmonised standards & normative documents**
(presumption of conformity to MID when correctly applied)
- **Guidance documents**, e.g. WELMEC Guides (Guidance documents represent a reference for ensuring consistent application of the directives by all those involved).
- **Commission Statement to WELMEC on Cooperation**

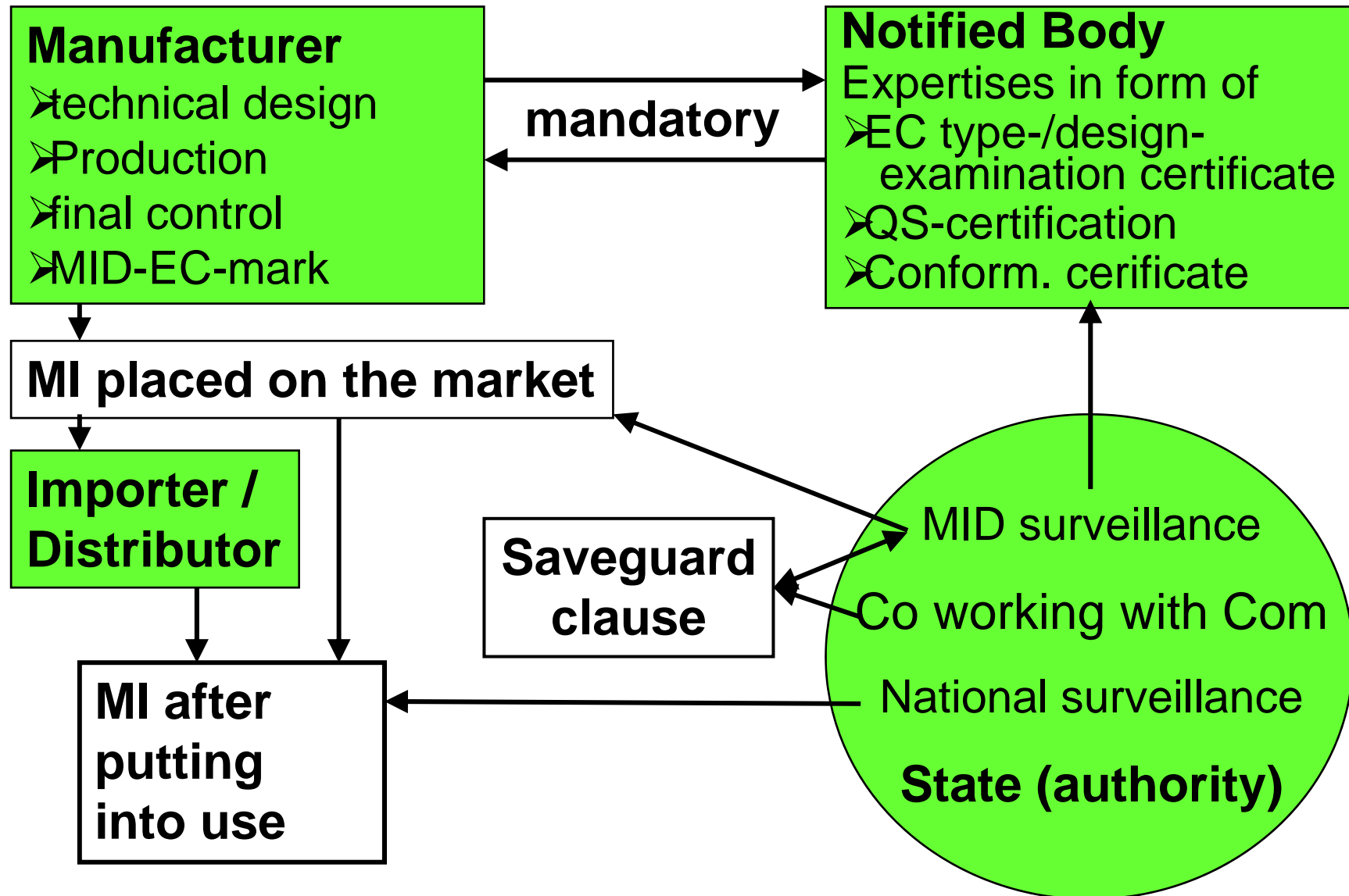
But Caution!!

All these tools are not a legally binding interpretation of the directive. The legally binding text remains that of Dir. 2001/22/EC.

More information:

<http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack>

Responsible actors (MID and Decision 768/2008/EC)



The Manufacturer (authorised representative)

- is as natural or legal person responsible for the conformity of the MI /-System: In respect of placing on the market under his own name, putting into use for his own purpose or by an end user
- is responsible to supply the national authorities with the necessary technical documentation and the EC type-/EC design examination certificate to a reasoned request. (no reaction causes a formal non-compliance → safeguard clause)
- shall take into account changes in harmon. Standards or in techn. specifications referenced in his certificate (→ product liability)
- may confer administrative duties to an authorised representative, at least: Keep certificates and documentation for nat. authorities and cooperate with authorities to eliminate risks

The manufacturer must be identifiable by his name or registered trade name/mark and address on the product

The manufacturer cannot share his responsibility with others, even when he is not or partly the producer of the measuring instrument!

National singularities: Language, Climate, Use

One type of a MI suitable for all states??

Language:

Conditions for correct use and communication with the MI must be kept for the user in an understandable language: E.g. inscriptions, marks, user manual, service/maintenance conditions (MID, Art. 6)

Climate:

The MI must be suitable for the local climatic conditions:
Temperature, Humidity (MID, Art. 8, Annex I, 1.3.1)

Local traditions of use:

Fuel dispenser: *Pricing is part of dispenser or point of sales,*

Business transaction: Paying cash or by electronic purse

Taximeter: *State controlled or company controlled tariff*

Automatic Weighing Instruments: *User specific requirements?*

Important for Manufacturers and Users

Manufacturer & state → Clear and defined purpose of the MI

- allowed environmental conditions for use
- defined purpose of use
- clear-cut markings on the MI (Identification, Sealing, Directives)
- instructions for service and maintenance
- easily understandable service and user manual → language!

Best prevention against a safeguard clause procedure!

(Mid, Art. 19 “Safeguard clause”: When a MI does not satisfy the essential requirements relating to the metrological performance of the MID, when correctly installed and used in accordance with the manufacturers instructions, it could be withdrawn from the market and their further placing on the market and use can be prohibited by the state!)

Obligation of Importers, Distributors

Importers and distributors on lower level

- are responsible for the formal correctness of CE/MID mark,
- shall ensure the product is accompanied with all necessary documentation in a language as determined by the state,
- shall indicate their name/registered trade name/mark and address on the MI,
- shall cooperate with national authorities if they assume that the product is not conform to the MID,
- shall ensure that the conformity of the MI to the directive will not jeopardised under their responsibility.

MID-obligations on member states

Transposition of MID into national legal metrology law

- Definitions (manufacturer, involved economic operators etc.)
- Essential requirements: Annex I and instrument specific MI-xxx for national regulated measurements (Optionality!)
- Responsibility for national notified bodies: Evaluation of the competence and impartiality of the bodies for the conformity assessment. (if accreditation: Reg. 765/2008/EC)
- Requirements to control the effectiveness of the MID-system by market surveillance on new measuring instruments by state authorities (Reg. 765/2008/EC, Dec. 768/2008/EC)
- How to perform safeguard clauses.
- Organising the cooperation with the Standing Committee and the Measuring Instruments Committee

Not regulated by MID → MI's after putting into use

Regulations additional to MID:

- Choice of measures which shall be controlled by legal metrology.
- Surveillance of correct use and functioning of the single MI's in the field - responsibilities (Internal market surveillance).
- Transition regulations for MI's with Certificates before Oct. 2006.
- National penalties (wrong use of MI's, liability of NB's, etc)
- Product liability (85/374/EEC liability for defective products).
- Language of inscriptions and user manuals.
- Maximum permissible errors for used MI's.
- How to finance the national activities



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**Thank you very much
for your attention!**