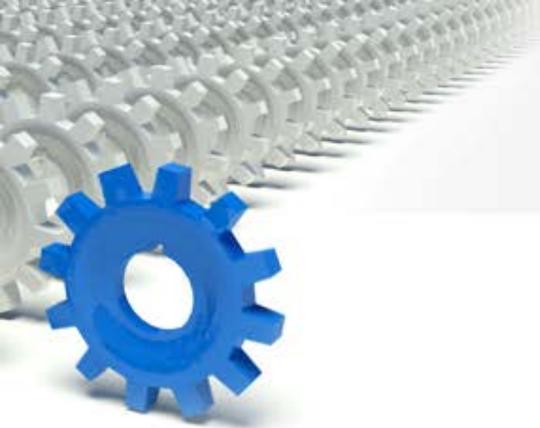


# CE-Marking

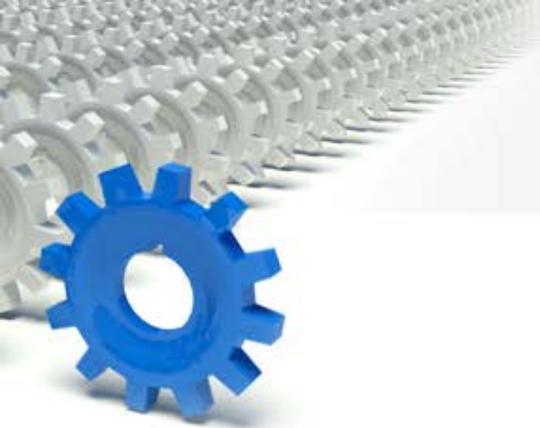
Presented by Yvonne Halpaus



**Machine/PPE/MDD/IVD...**

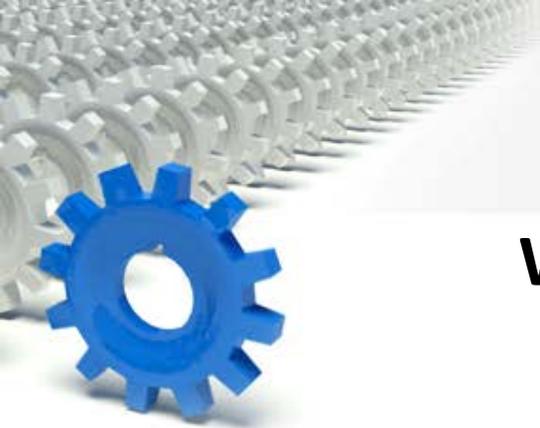
**Complies with European Directives and its Harmonized Standards, compliance proof is in existence.**

**75% of all products exported to the EU require CE-Marking.**



## **CE Marking is the obligation of:**

- 1. Manufacturer for compliance**
- 2. Importer-Distributor-End User**  
**Must import CE compliant products only**
- 3. EU Authorized Representative on behalf of Manufacturer for regulatory affairs.**



# Who is the Manufacturer

## In Plain English:

**The party that places its name OR trademark on the nameplate or label.**

**Responsible/liable for : design, production + CE conformity**



## **EU Directives vs. Harmonized Standards**

**CE compliance is required in accordance with the Directives' Essential Requirements**

**Harmonized Standards are state-of-the art support documents that have to be used!**



# EC Declaration of Conformity (Machinery)

## For Illustrative Use Only

(Not to be relied upon for accuracy)

**Manufacturers Name:**

**Manufacturers Address:**

Declare that the machinery described below complies with applicable health and safety requirements of Part 1 of Annex 1 of the Machinery Directive 2006/42/EC and EMC Directive 2014/30/EU.

**Description:**

**Model/Type Number:**

**Sizes:**

**Commercial Name:**

**Serial Number:(If Applicable)**

The following standards have either been referred to or been complied with in part or in full as relevant:

ENISO 12100-2	Machinery Safety	Basic Concepts, general principals for design-Part 2: Technical Principals and specifications
EN 12345	Machinery Safety	Safety Related Parts of Control Systems-Part 1:General Principals for Design
EN 13857	Machinery Safety	Safety distances to prevent danger zones being reached by the upper limbs or lower limbs
EN 908	Machinery Safety	Pumps and Pump Units for liquids. Common safety requirements
EN 953	Machinery Safety	General requirements for the design and construction of guards
EN61000-6-4:2001	EMC	Generic Emission's standard

Full Name of Responsible person and place of signing:

Position:

Signature:

Date:

Place: City/State



QNET BV  
Kantstraat 19  
NL-5076NP Haaren  
The Netherlands

