Bilfinger Tebodin
CE marking in the process industry

By Albert Steltenpool

Bilfinger Tebodin – part of Bilfinger Group

Bilfinger SE – a German company working globally, as a leading service provider for the process industry. Bilfinger Tebodin is a part of its Engineering & Maintenance service line.

Employees	About 30 000
Revenue 2020	€3,46 billion

Bilfinger Tebodin worldwide

Leading consultancy, engineering, process design and management company

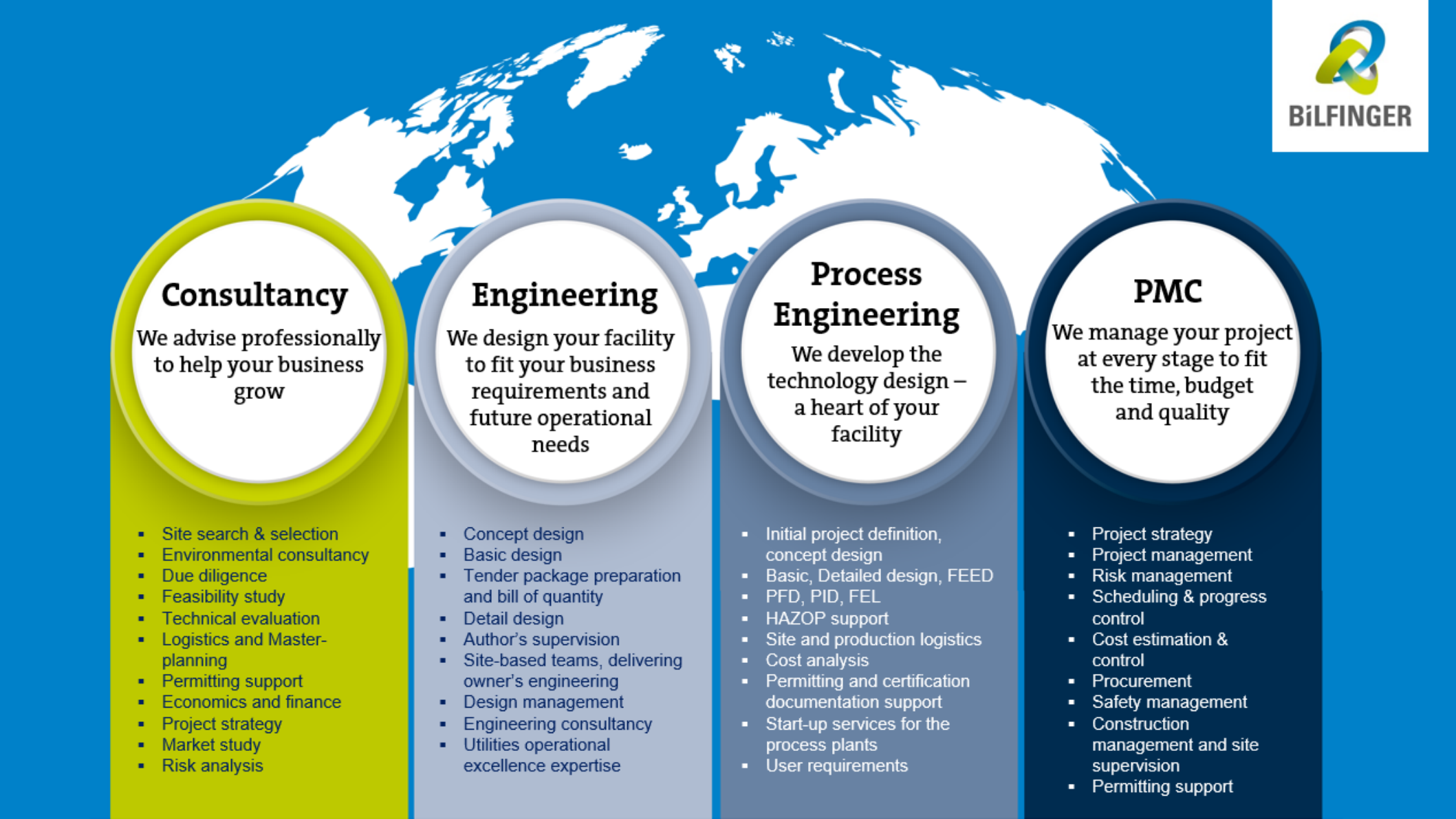
- Founded in 1945, the Hague, the Netherlands
- > 75% of turnover – repetitive business
- 27 offices in 12 countries In Europe
- Part of Bilfinger Group since 2012
- 1,600 consultants and engineers in Europe
- www.tebodin.bilfinger.com

World presence

North West Europe
Belgium, Germany, The Netherlands, United Kingdom

Central and Eastern Europe
Czech Republic, Hungary, Poland, Romania, Serbia, Russia, Ukraine, Slovakia

Middle East
Bahrain, Oman, Qatar, Saudi Arabia, United Arab Emirates



BILFINGER

Consultancy

We advise professionally to help your business grow

- Site search & selection
- Environmental consultancy
- Due diligence
- Feasibility study
- Technical evaluation
- Logistics and Master-planning
- Permitting support
- Economics and finance
- Project strategy
- Market study
- Risk analysis

Engineering

We design your facility to fit your business requirements and future operational needs

- Concept design
- Basic design
- Tender package preparation and bill of quantity
- Detail design
- Author's supervision
- Site-based teams, delivering owner's engineering
- Design management
- Engineering consultancy
- Utilities operational excellence expertise

Process Engineering

We develop the technology design – a heart of your facility

- Initial project definition, concept design
- Basic, Detailed design, FEED
- PFD, PID, FEL
- HAZOP support
- Site and production logistics
- Cost analysis
- Permitting and certification documentation support
- Start-up services for the process plants
- User requirements

PMC

We manage your project at every stage to fit the time, budget and quality

- Project strategy
- Project management
- Risk management
- Scheduling & progress control
- Cost estimation & control
- Procurement
- Safety management
- Construction management and site supervision
- Permitting support

Your speaker:
Albert Steltenpool

Sr. Consultant Environmental & Safety Management

At Technical Safety Department – Tebodin Consultancy

Working at Tebodin (Velsen) for some 23 years

Education: Environmental Engineering (grad. 1992) - Rijkshogeschool Ijsselland – Deventer

Fields of expertise: HAZID, HAZOP, CE marking (MD, PED), ATEX, Arbo Decree, PGS guidelines (especially 13, 15, 28, 29, 30, 31), H&S coordination design and construction phase

and last but not least: HSE engineering (:managing HSE compliance in engineering projects)

Specific interests/hobbies: history & writer of essays and songs (with the band Nes)

CE marking in the process industry
Agenda

Introduction

Basics on CE marking (most important directives for industry)
- Machinery Directive (MD)
- Pressure Equipment Directive (PED)
- (excluding ATEX for now)

Legal framework process versus machine safety

CE marking procedure

Challenges:
-What is an assembly?
- Who is the manufacturer?

How does the process industry deal with these?

Conformité Européenne

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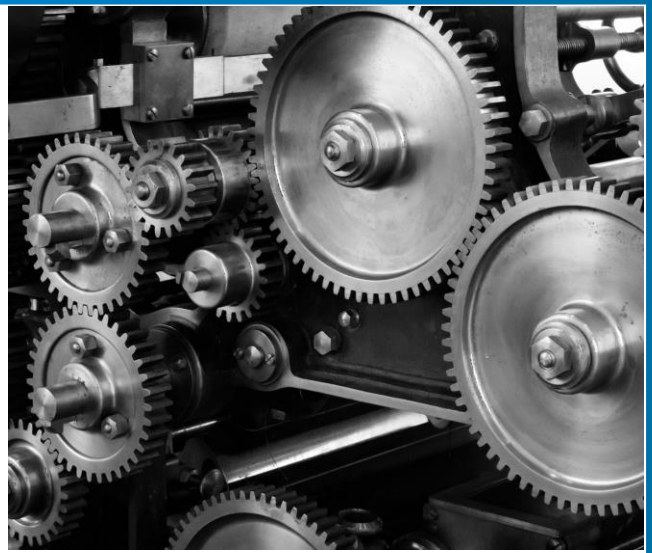
Conformity with the European Directives

CE marking in the process industry

Machinery Directive → Ww besluit Machines
(future → Machinery regulation)



2006/42/EC, (in former revision) applicable since 1995

Goal:

- The Directive promotes harmonization through a combination of mandatory health and safety requirements (annex I) and voluntary harmonized standards.
- It stimulates the free trade of machinery within the EU and
- ensures a high level of safety for EU workers and citizens.

Machinery (definition):

"an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application."

See Directive for additional definitions (e.g. hoisting eq.) and exclusions

CE marking in the process industry

Pressure Equipment Directive (PED) → Ww Besluit Drukapparatuur

2014/68/EU, (in former revision) drawn up ’97, applicable since 2002

Goal:

- Quite the same as for the Machinery directive, but for pressure equipment.

Pressure equipment (definition):

“means vessels, piping, safety accessories and pressure accessories, including, where applicable, elements attached to pressurised parts, such as flanges, nozzles, couplings, supports, lifting lugs; applies to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0,5 bar.”

See Directive for additional definitions (e.g. safety devices) and exclusions

Framework Machine safety versus Process safety

Process safety: keep hazardous substances contained!

	Process safety	**Machine safety**
European framework	Sevezo III Directive / PED	(Working tools/) Machinery Directive
National legal framework	Besluit Risico Zware Ongevallen, WBDA/ Arbowet / Omgevingswet	Arbowet (: Law on working conditions) Warenwetbesluit machines
Standards for risk analysis	NEN-IEC 61882:2001: Hazard and operability studies (HAZOP studies) - Application guide	EN ISO 12100: Safety of Machinery – Risk Assessment and Risk Reduction
Standards for Safety instrumented systems	IEC 61508 and IEC 61511	EN/IEC 62061 (SIL) or EN ISO 13849 (PL)

CE marking procedure

Steps to be followed by manufacturer (MD/PED)

1) Determine ‘manufacturer’; who is responsible for safe design/delivery/installation?

2) Identify applicable directives & standards

3) Draw up a Technical (design & installation) File

4) Execute necessary risk analysis (e.g. FMEA, HAZOP, SIL, Lay out review)

5) Draw up instructions/ execute trainings for safe use

(Notified bodies and/or NL-CBI to be involved?)

6) Verify the follow up of all risk analysis studies & draw up a declaration of conformity (or a declaration for safe use)

CE marking in the process industry

MD & PED: challenges

Definitions and responsibilities related to single pieces of equipment are quite clear

But when looking at assemblies? → of Machinery and/or pressure equipment

For instance when building a new plant facility?

Who is the (CE) manufacturer?

- Manufacturer/supplier of a single piece of equipment;
- Manufacturer/supplier of a package unit;
- EPC contractor
- Engineering company;
- (Mechanical) contractor;
- Client?

CE marking in the process industry

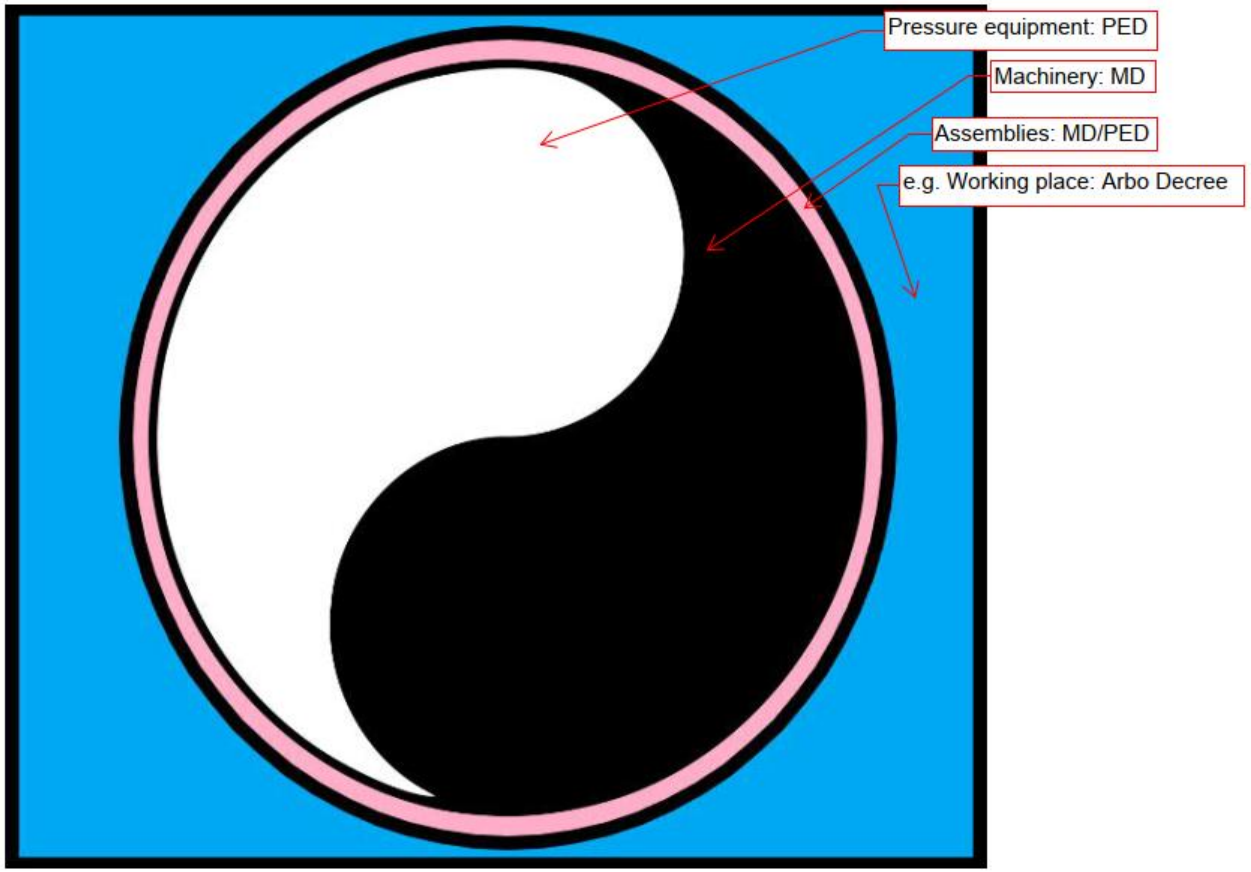
MD ‘Blue guide’ about assemblies versus production facilities

§38 Assemblies of machinery

The definition of assemblies of machinery does not extend to a complete industrial plant consisting of a number of production lines each made up of a number of machines, assemblies of machinery and other equipment, even if they are controlled together by a single production control system. Only if the plant (which may be any combination of machinery, partly completed machinery and other equipment resulting in machinery subject to the Machinery Directive) forms a single integrated line is it subject to the Machinery Directive as an assembly. So for the purpose of applying the Machinery Directive, most industrial plants can be divided into different sections, each of which may be a distinct assembly (of machinery) or even an independent machine (e.g. a mixing vessel). Even a single production line may be divided into separate assemblies and/or

CE marking versus industrial installations

Schematically



CE marking in the process industry

Assembling/system integration: “Keuring van ingebruikname (WBDA)”

The awareness / sense of urgency – depending on who it concerns – regarding CE marking (of assemblies) in the process industry is limited:

- More focus on (external/) process risks than on Machinery/e.g. ergonomic risks
- “grey zones” between equipment (→ assemblies) → process installations
- Limited enforcement Labour inspectorate on Machinery Directive in Process industry

The main exception is equipment/systems subjected to a “Keuring van Ingebruikname WBDA” → which regards a national addition to the PED (…which compensates…)

System integration:

- By controlling (to be assessed at HAZOP) → also (partly) fulfils requirements of Machinery Directive *“1.2.1. Safety and reliability of control systems: Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising”*

CE marking in engineering projects
Tips & tricks

- Always purchase equipment with CE marking, fabricated according to harmonized standards, unless…
- When purchasing (integrated) package units; lay down a high responsibility on safety (CE) at suppliers (for as far as practical and reasonable)
- Determine and lay down a CE strategy for purchasing with the engineering team and with client
- Agree on how to guard CE expectations with the engineering team (Vendor Document Control)
- But in the risk/compliance assessment: have a ‘holistic view’: Safety first!
- 3D design tools have a high advantage in assessing risks during design phase, but use them well (well prepared, with multi disciplinary view & don't let the means become the end)
- Pay enough attention to the safety instructions for your personnel
- Track and close all (safety) actions and document this!

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