

**CONFORMITY ASSESSMENT SERVICES
IN SCOPE OF CE MARKING**



A. SCOPE UNDER LIFT DIRECTIVE (95/16/EC)		
Full quality assurance	Module H	(95/16/EC Annex-IX)
Production quality assurance	Module D	(95/16/EC Annex-XIV)
Product quality assurance	Module E	(95/16/EC Annex-XII)
Unit verification	Module G	(95/16/EC Annex X)
EC type-examination	Module B	(95/16/EC Annex V-b)
Product verification	Module F	(95/16/EC Annex VI)

B. SCOPE UNDER CONSTRUCTION PRODUCTS REGULATION (305/2011)

Product family, product/Intended use	Technical specification	Conformity System
Aggregates <ul style="list-style-type: none">• Aggregates for concrete.• Aggregates for bituminous mixtures and surface treatments for roads, airfields and other trafficked areas.• Lightweight aggregates for concrete, mortar and grout.• Lightweight aggregates for bituminous mixtures and surface treatments and for unbound and bound applications.• Aggregates for mortar.• Aggregates for unbound and hydraulically bound materials for use in civil engineering work and road construction.• Aggregates for railway ballast	TS 706 EN 12620 TS EN 13043 TS 1114 EN 13055-1 TS EN 13055-2 TS 2717 EN 13139 TS EN 13242 TS EN 13450	System 2+
Armourstone (for structures requiring hydraulic protection and control)	TS EN 13383-1	System 2+

B. SCOPE UNDER CONSTRUCTION PRODUCTS REGULATION (305/2011)

Product family, product/Intended use	Technical specification	Conformity System
<p>Cements</p> <ul style="list-style-type: none"> • Common cements, including common cements with low heat of hydration and sulphate resisting common cements as well as low early strength blast furnace cements and low early strength blast furnace cements with low heat of hydration. • Portland cements. • Portland composite cements; <ul style="list-style-type: none"> ○ Portland-slag cement ○ Portland-silica fume cement ○ Portland-pozzolana cement ○ Portland-fly ash cement ○ Portland-burnt shale cement ○ Portland-limestone cement • Blastfurnace cements. • Pozzolanic cements. • Composite cements. 	<p>TS EN 197-1</p>	<p>System 1+</p>
<p>Building limes, including:</p> <ul style="list-style-type: none"> • Calcium limes. • Dolomitic limes. • Hydraulic limes (preparation of concrete, mortar, grout and other mixes for construction and for the manufacture of construction products). 	<p>TS EN 459-1</p>	<p>System 2+</p>
<p>Masonry units <u>Category I</u> (in walls, columns and partitions)</p> <ul style="list-style-type: none"> • Clay masonry units. • Calcium silicate masonry units. • Aggregate concrete masonry units (Dense and lightweight aggregates). • Autoclaved aerated concrete masonry units. • Manufactured stone masonry units. • Natural stone masonry units. 	<p>TS EN 771-1 TS EN 771-2 TS EN 771-3 TS EN 771-4 TS EN 771-5 TS EN 771-6</p>	<p>System 2+</p>

B. SCOPE UNDER CONSTRUCTION PRODUCTS REGULATION (305/2011)

Product family, product/Intended use	Technical specification	Conformity System
<p>Admixtures (for concrete, mortar and grout)</p> <ul style="list-style-type: none"> • Concrete admixtures • Admixtures for masonry mortar • Admixtures for grout for pre-stressing tendons • Admixtures for sprayed concrete 	<p>TS EN 934-2 TS EN 934-3 TS EN 934-4 TS EN 934-5</p>	<p>System 2+</p>
<p>Bituminous mixtures (for road construction and surface treatment of roads)</p> <ul style="list-style-type: none"> • Asphalt Concrete. • Asphalt Concrete for very thin layers. • Soft Asphalt. • Hot Rolled Asphalt. • Stone Mastic Asphalt. • Mastic Asphalt. • Porous Asphalt. 	<p>TS EN 13108-1 TS EN 13108-2 TS EN 13108-3 TS EN 13108-4 TS EN 13108-5 TS EN 13108-6 TS EN 13108-7</p>	<p>System 2+</p>
<p>Bitumen and bituminous binders:</p> <ul style="list-style-type: none"> • Paving grade bitumen. • Cationic bituminous emulsions. • Sub-family: Hard paving grade bitumen • Sub-family: polymer modified bitumen. • Cut-back and fluxed bituminous binders. 	<p>TS EN 12591 TS EN 13808 TS EN 13924 TS EN 14023 TS EN 15322</p>	<p>System 2+</p>
<p>(Membranes) Flexible sheets for waterproofing:</p> <ul style="list-style-type: none"> • Reinforced bitumen sheets for roof waterproofing. • Plastic and rubber sheets for roof waterproofing. • Plastic and rubber damp proof sheets including plastic and rubber basement tanking sheet. • Bitumen damp proof sheets including bitumen basement tanking sheets. • Reinforced bitumen sheets for waterproofing of concrete bridge decks and other trafficked areas of concrete. 	<p>TS EN 13707 TS EN 13956 TS EN 13967 TS EN 13969 TS EN 14695</p>	<p>System 2+</p>

B. SCOPE UNDER CONSTRUCTION PRODUCTS REGULATION (305/2011)

Product family, product/Intended use	Technical specification	Conformity System
Products and systems for the protection and repair of concrete structures: <ul style="list-style-type: none">• Surface protection systems for concrete.• Structural and non-structural repair.• Structural bonding.• Concrete injection.• Anchoring of reinforcing steel bar.• Reinforcement corrosion protection.	TS EN 1504-2 TS EN 1504-3 TS EN 1504-4 TS EN 1504-5 TS EN 1504-6 TS EN 1504-7	System 2+
Factory-made, designed masonry mortars (in walls, columns and partitions)	TS EN 998-2	System 2+

B. SCOPE UNDER CONSTRUCTION PRODUCTS REGULATION (305/2011)

Product family, product/Intended use	Technical specification	Conformity System
<p>Prefabricated chimneys (storey height elements), flue liners (elements or blocks), multi-shell chimney (elements or blocks), single walled chimneys and attached chimneys (chimneys):</p> <ul style="list-style-type: none"> • Clay/ceramic flue liners • Clay/ceramic flue blocks for single wall chimneys. • System chimney products. • Metal liners and connecting flue pipes. • Concrete flue liners. • Concrete flue blocks. • Concrete outer wall elements. • System chimneys with clay/ceramic flue liners - Part 1: Requirements and test methods for soot-fire resistance. • System chimneys with clay/ceramic flue liners - Part 2: Requirements and test methods under wet conditions. • System chimneys with clay/ceramic flue liners - Part 3: Requirements and test methods for air flue system chimneys. • Clay/ceramic outer walls for system chimneys. • Free-standing chimneys - Part 5: Material for brick liners. • Free-standing chimneys - Part 7: Product specifications of cylindrical steel fabrications for use in single wall steel chimneys and steel liners. • System chimneys with plastic flue liners. • Requirements and test methods for metal chimneys and material independent air supply ducts for room-sealed heating applications - Part 1: Vertical air/flue terminals for C6-type appliances. • Requirements and test methods for metal chimneys and material independent air supply ducts for room-sealed heating applications - Part 2: Flue and air supply ducts for room sealed appliances. 	<p>TS EN 1457:1999</p> <p>TS EN 1806</p> <p>TS EN 1856-1</p> <p>TS EN 1856-2</p> <p>TS EN 1857</p> <p>TS EN 1858</p> <p>TS EN 12446</p> <p>TS EN 13063-1</p> <p>TS EN 13063-2</p> <p>TS EN 13063-3</p> <p>TS EN 13069</p> <p>TS EN 13084-5</p> <p>TS EN 13084-7</p> <p>TS EN 14471</p> <p>TS EN 14989-1</p> <p>TS EN 14989-2</p>	<p>System 2+</p>

B. SCOPE UNDER CONSTRUCTION PRODUCTS REGULATION (305/2011)

Product family, product/Intended use	Technical specification	Conformity System
<p>Unfaced overlaid and veneered or coated wood-based panels (for structural elements in internal or external applications)</p>	<p>TS EN 13986</p>	<p>System 2+</p>
<p>Structural metallic products and ancillaries (1/4) :</p> <p>Structural metallic sections/profiles: hot rolled, cold formed or otherwise produced sections/profiles with various shapes (T, L, H, U, Z, I, channels, angle, hollow, tubes), flat products (plate, sheet, strip), bars, castings, forgings made of various metallic materials, unprotected or protected against corrosion by coating (to be used in metal structures or in composite metal and concrete structures)</p> <ul style="list-style-type: none"> • Hot rolled products of structural steels. • Stainless steels - Sheet/plate and strip of corrosion resisting steels for construction purposes • Stainless steels - bars, rods, wire, sections and bright products of corrosion resisting, steels for construction purposes • Hot finished structural hollow sections of non-alloy and fine grain steels. • Cold formed welded structural hollow sections of non-alloy and fine grain steels. • Steel castings for structural uses - Structural metallic sections and profiles. • Steels for quenching and tempering for construction purposes. • Aluminium and aluminium alloys - Structural products for construction works. 	<p>TS EN 10025-1</p> <p>TS EN 10088-4</p> <p>TS EN 10088-5</p> <p>TS EN 10210-1</p> <p>TS EN 10219-1</p> <p>TS EN 10340</p> <p>TS EN 10343</p> <p>TS EN 15088</p>	<p>System 2+</p>
<p>Welding materials (for uses in structural metallic works)</p> <ul style="list-style-type: none"> • Welding consumables - General product standard for filler metals and fluxes for fusion welding of metallic materials. 	<p>TS EN 13479</p>	<p>System 2+</p>

B. SCOPE UNDER CONSTRUCTION PRODUCTS REGULATION (305/2011)

Product family, product/Intended use	Technical specification	Conformity System
<p>Structural connectors: metallic rivets, bolts (nuts and washers) and H.R. bolts (high strength friction grip bolts), studs, screws, railway fasteners (for uses in structural metallic works).</p> <ul style="list-style-type: none"> • High-strength structural bolting assemblies for preloading – structural connectors. • Non-preloaded structural bolting assemblies - structural connectors. 	<p>TS EN 14399-1 TS EN 15048-1</p>	<p>System 2+</p>
<p>Precast normal/lightweight/autoclaved aerated concrete products (1/1) : - Precast normal/lightweight/autoclaved aerated concrete products (for structural use)</p> <ul style="list-style-type: none"> • Hollow core slabs • Prefabricated reinforced components of lightweight aggregate concrete with open structure with structural or non-structural reinforcement • Floor slats for livestock • Foundation piles • Masts and poles • Ribbed floor elements • Linear structural elements • Special roof elements • Floor plates for floor systems • Requirements for reinforced garages monolithic or consisting of single sections with room dimensions • Stairs • Box culverts • Foundation elements • Wall elements • Beams • Concrete blocks for beam-and-block floor systems • Clay blocks for beam-and-block floor systems • EPS blocks for beam-and-block floor systems • Bridge elements. • Retaining wall elements. 	<p>TS EN 1168 TS EN 1520 TS EN 12737 TS EN 12794 TS EN 12843 TS EN 13224 TS EN 13225 TS EN 13693 TS EN 13747 TS EN 13978-1 TS EN 14843 TS EN 14844 TS EN 14991 TS EN 14992 TS EN 15037-1 TS EN 15037-2 TS EN 15037-3 TS EN 15037-4 TS EN 15050 TS EN 15258</p>	<p>System 2+</p>

B. SCOPE UNDER CONSTRUCTION PRODUCTS REGULATION (305/2011)

Product family, product/Intended use	Technical specification	Conformity System
Road construction products (1/2) : Surface treatments (for surface treatments of roads) <ul style="list-style-type: none">• Surface dressing• Slurry surfacing	TS EN 12271 TS EN 12273	System 2+
Structural metallic products and ancillaries (2/4) : Structural metallic construction members: finished metallic products such as trusses, girders, columns, stairs, ground piles, bearing piles and sheet piling, cut to size sections designed for certain applications, and rails and sleepers. They can be unprotected or protected against corrosion by coating, welded or not. (for uses in work's frames and foundations) <ul style="list-style-type: none">• Execution of steel structures and aluminium structures<ul style="list-style-type: none">- Steel and aluminium structural components	TS EN 1090-1	System 2+

C. SCOPE UNDER NEW HOT WATER BOILERS DIRECTIVE (92/42/EC)

Product Group	Modules	Related Standards
Gas-fired central heating boilers	Module B: EC Type Examination Module D: Production Quality Assurance Module E: Product Quality Assurance	TS EN 303-1 TS EN 303-3 TS EN 297 TS EN 483 TS EN 625 TS EN 677
Heating Boilers with atomizing oil burners	Module B: EC Type Examination Module D: Production Quality Assurance Module E: Product Quality Assurance	TS EN 303-1 TS EN 303-2 TS EN 297 TS EN 483 TS EN 625 TS EN 677

D. SCOPE UNDER IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE (98/79/EC)

Product Group	Module
<p>VIVD 0300 List B Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating</p> <p>IVD 0301 Anti-Duffy and anti-Kidd</p> <p>IVD 0302 Irregular anti-erythrocytic antibodies</p> <p>IVD 0303 Congenital infections: rubella, toxoplasmosis</p> <p>IVD 0304 Hereditary disease: phenylketonuria</p> <p>IVD 0305 Human infections: cytomegalovirus, chlamydia</p> <p>IVD 0306 HLA tissue groups: DR, A, B</p> <p>IVD 0307 Tumoral marker: PSA</p> <p>IVD 0308 Risk of trisomy 21 (incl.software)</p> <p>IVD 0309 Device for self-diagnosis: device for the measurement of blood sugar</p> <p>IVD 0400 Devices for self-testing</p> <p>IVD 0401 Clinical Chemistry</p> <p>IVD 0402 Haematology</p> <p>IVD 0403 Immunology</p> <p>IVD 0404 Molecular biology</p> <p>IVD 0405 Pregnancy and ovulation</p> <p>IVD 0406 Specimen receptacles</p>	<p>Module A+: EC Declaration of Conformity and Design Examination (Annex III)</p> <p>Module D: Production Quality Assurance (Annex VII)</p> <p>Module H: Full Quality Assurance (Annex IV)</p>

E. SCOPE UNDER APPLIANCES BURNING GASEOUS FUELS (2009/142/EC)

Product Groups	Modules	Related Standards
Domestic cooking appliances burning gaseous fuel	Module B: EC Type Examination Module D: Production Quality Assurance Module E: Product Quality Assurance	TS 616-1-1 TS EN 30-1-1 TS 616-2-1 TS EN 30-2-1 TS 616-1-2 TS EN 30-1-2 TS 616-2-2 TS EN 30-2-2
Central heating boilers burning gaseous fuel	Module B: EC Type Examination Module D: Production Quality Assurance Module E: Product Quality Assurance	TS EN 303-1 TS EN 303-3 TS EN 297 TS EN 483 TS EN 625 TS EN 677
Industrial cooking appliances burning gaseous fuel	Module B: EC Type Examination Module D: Production Quality Assurance Module E: Product Quality Assurance	TS EN 203 Series
Independent gas-fired convection heaters	Module B: EC Type Examination Module D: Production Quality Assurance Module E: Product Quality Assurance	TS EN 613
Liquefied petroleum gas appliances. Flueless non-domestic space heaters not exceeding 10 kW	Module B: EC Type Examination Module D: Production Quality Assurance Module E: Product Quality Assurance	TS EN 461

F. SCOPE UNDER PERSONAL PROTECTIVE EQUIPMENT DIRECTIVE (89/686/EEC)

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives
*Equipment providing foot and leg protection	<p>EC type-examination</p> <p>System for ensuring EC quality of production by means of monitoring EC quality control system for the final product</p>	<p>Art.10</p> <p>Art.11B</p> <p>Art.11A</p>
<p>Equipment providing chest and groin protection</p> <p>Equipment providing eye protection</p> <p>Equipment providing face protection</p>	<p>System for ensuring EC quality of production by means of monitoring EC quality control system for the final product</p>	<p>Art.11B</p> <p>Art.11A</p>
<p>*Equipment providing general body protection (clothing</p> <p>Equipment providing head protection</p> <p>Equipment providing hand and arm protection</p> <p>Equipment providing hearing protection</p> <p>Equipment providing respiratory protection</p>	<p>System for ensuring EC quality of production by means of monitoring EC quality control system for the final product</p>	<p>Art.11B</p> <p>Art.11A</p>

G. SCOPE UNDER PRESSURE EQUIPMENT DIRECTIVE (97/23/EC)

<u>Module B1</u>	<u>Design Examination</u>
Module D and Module D1	Production Quality Assurance
Module E and Module E1	Product Quality Assurance
Module H	Full Quality Assurance
Module H1	Full Quality Assurance with design examination and special surveillance of the final assessment
ANNEX 1 Art. 3.1.2	Welding Procedure Approval
ANNEX 1 Art. 3.1.3	Approval of Welding Personnel
ANNEX 1 Art. 3.1.3	Approval of Non-Destructive Testing Personnel

H. SCOPE UNDER MEDICAL DEVICE DIRECTIVE (93/42/EEC)

Product Group	Module
<ul style="list-style-type: none"> • (All products on the scope of the directive) • MD 0100 General non-active, non-implantable medical devices • MD 0101 Non-active devices for anaesthesia, emergency and intensive care • MD 0102 Non-active devices for injection, transfusion and dialysis • MD 0103 Non-active orthopaedic and rehabilitation devices • MD 0104 Non-active medical devices with measuring function • MD 0105 Non-active ophthalmologic devices • MD 0106 Non-active instruments • MD 0107 Contraceptive medical devices • MD 0108 Non-active medical devices for disinfecting, cleaning, rinsing • MD 0109 Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART) • MD 0200 Non-active implants • MD 0201 Non-active cardiovascular implants • MD 0202 Non-active orthopaedic implants • MD 0203 Non-active functional implants • MD 0204 Non-active soft tissue implants • MD 0300 Devices for wound care • MD 0301 Bandages and wound dressings • MD 0302 Suture materials and clamps • MD 0303 Other medical devices for wound care • MD 0400 Non-active dental devices and accessories • MD 0401 Non-active dental equipment and instruments • MD 0402 Dental materials • MD 0403 Dental implants • MD 1100 General active medical devices 	<p>Module B: Type Examination (Annex III)</p> <p>Module D: Production Quality Assurance (Annex V)</p> <p>Module Dbis: Production Quality Assurance (Annex V)</p> <p>(For Class IIa and Class I sterile and Class I measuring function devices)</p> <p>Module E: Product Quality Assurance (Annex IV)</p> <p>Module Ebis: Production Quality Assurance (Annex VI)</p> <p>(For Class IIa and Class I sterile and Class I measuring function devices)</p> <p>Module H: Full Quality Assurance (Annex II)</p> <p>Module Hbis: Full Quality Assurance and Design Examination (Annex II)</p>

<ul style="list-style-type: none">• MD 1101 Devices for extra-corporal circulation, infusion and haemopheresis• MD 1102 Respiratory devices, devices including hyberbaric chambers for• oxygen therapy, inhalation anaesthesia• MD 1103 Devices for stimulation or inhibition• MD 1104 Active surgical devices• MD 1105 Active ophthalmologic devices• MD 1106 Active dental devices• MD 1107 Active devices for disinfection and sterilisation• MD 1108 Active rehabilitation devices and active protheses• MD 1109 Active devices for patient positioning and transport• MD 1110 Active devices for in vitro fertilization (IVF) and assisted• reproductive technologies (ART)• MD 1111 Software• MD 1200 Devices for imaging• MD 1201 Imaging devices utilising ionizing radiation• MD 1202 Imaging devices utilising non-ionizing radiation• MD 1300 Monitoring devices• MD 1301 Monitoring devices of non-vital physiological parameters• MD 1302 Monitoring devices of vital physiological parameters• MD 1400 Devices for radiation therapy and thermo therapy• MD 1401 Devices utilizing ionizing radiation• MD 1402 Devices utilizing non-ionizing radiation• MD 1403 Devices for hyperthermia/hypothermia• MD 1404 Devices for (extracorpoal) shock-wave therapy (lithotripsy)	
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I. SCOPE UNDER NON-AUTOMATIC WEIGHING INSTRUMENTS DIRECTIVE (2009/23/EC)

Product Group	Module
Non-Automatic Weighing Instruments	EC Type Examination (Module B) Production Quality Assurance (Module D)

J. MEASURING INSTRUMENTS DIRECTIVE (2004/22/EC)

Product Group	Module
Water Meters (Annex MI-001)	-Type-examination Annex B -Declaration of conformity to type based on quality assurance of the production process Annex D -Declaration of conformity to type based on product verification Annex F -Declaration of conformity based on full quality assurance plus design examination Annex H1
Gas Meters and Volume Conversion Devices (Annex MI-002)	Type-examination Annex B -Declaration of conformity to type based on quality assurance of the production process Annex D -Declaration of conformity to type based on product verification Annex F -Declaration of conformity based on full quality assurance plus design examination Annex H1
Active Electrical Energy Meters (Annex MI-003)	Type-examination Annex B -Declaration of conformity to type based on quality assurance of the production process Annex D -Declaration of conformity to type based on product verification Annex F -Declaration of conformity based on full quality assurance plus design examination Annex H1

**K. EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE
ATMOSPHERES (94/9/EC)**

Product Group	Module
Internal control of production + receipt of technical file	Art. 8.1 (b) (ii)
Product quality assurance	Annex VII
Unit verification	Annex IX
Production quality assurance	Annex IV
Conformity to type	Annex VI
Product verification	Annex V
EC type-examination	Annex III