SCHICHTWERK · ANWENDUNGSWERK

Application Guide

Application Classes & Regulatory Requirements

Which sector triggers which standard and certification

From flowerpot to medical device – EU/AT/DACH

Schichtwerk Vienna · contract manufacturer · office@schicht-werk.eu · schicht-werk.eu

Public strand · Version 1.0 · March 2026

No cooperation with the weapons, military or defence industry

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Introduction: Why the Application Decides Everything

One and the same manufacturing process generates entirely different obligations – depending on what the part is intended for. A decorative flowerpot is subject to virtually no product-specific regulation; a dental component falls under the Medical Device Regulation; a children's toy must meet toy safety; a load-bearing technical part requires a strength verification.

This guide assigns typical applications to classes and names the requirements each triggers. It describes the general legal framework and does not replace case-by-case assessment.

Core principle: the intended use defines the obligations

Not the process (FDM/SLA) determines regulation, but the intended purpose.

Even the marketing/claim of a product can place it into a regulated category (e.g. "for pain relief" → medical device).

In case of doubt the stricter classification applies; the burden of proof lies with the party placing the product on the market.

Application-Class Matrix

The central overview: application class → typical examples → essential requirement → triggered legal framework (EU).

Class	Examples	Essential requirement	Legal framework (EU)
1 Decorative	flowerpot, figurine, vase	none product-specific; general GPSR	GPSR 2023/988
2 Functional non-critical	holder, housing, organizer	fitness for use	GPSR 2023/988
3 Technically loaded	gear, clamp, jig	strength verification (testing)	GPSR; poss. Machinery Reg.
4 Food contact	cutter, mould	migration conformity	EU 1935/2004 + 10/2011
5 Toy (< 14 yrs)	play figure, building block	toy safety + CE	Reg. 2025/2509 / Dir. 2009/48
6 Medical/Dental	model, splint, drill guide	conformity per class	MDR 2017/745
7 Assistive/Orthopaedic	grip aid, orthosis	depends on intended purpose	MDR or comfort product
8 Safety component/Machine	guard component	conformity + CE	Machinery Reg. 2023/1230
9 Construction product	load-bearing element	declaration of performance	CPR 305/2011

Reading the obligation-depth scale

Class 1–2: low obligation depth – general product safety usually suffices.

Class 3–4: medium depth – verification/conformity is material-dependent.

Class 5–9: high depth – specific regulations, frequently CE/conformity assessment.

Class 1–2 · Decorative & Functional Non-critical

Typical products: decorative items, figurines, vases, flowerpots, organizers, housing parts without safety function, holders without critical load.

Requirements

- General product safety under GPSR (EU) 2023/988 – the product must be safe under intended and foreseeable use.
- No product-specific certification required.
- On sale: minimum marking (manufacturer/placer identifiable).
- Contract-manufacturer logic: product responsibility per order and agreement.

Critical point

Even “harmless” decor can slip into a higher class: a figurine marketed as a children’s item becomes a toy; a drinking cup becomes food-contact material.

Class 3 · Technically Loaded Parts

Typical products: gears, clamps, loaded holders, jigs, spare parts, mechanically stressed functional parts.

Requirements

- Strength verification: load assumption + material property + safety factor; tensile test (ISO 527 / ASTM D638) where needed.
- Consideration of anisotropy (Z-strength, see WERKSTOFFWERK/monograph).
- Documentation: material, print parameters, test record.
- If the part becomes part of a machine or a safety component → Class 8 (Machinery Regulation).

Critical point: prototype vs. series part

Clearly mark prototypes/proof-of-concept without safety guarantee as such.

Series functional parts with defined load require first-article inspection and test evidence.

No safety-critical load paths without external test verification.

Class 4 · Food Contact

Legal framework

Food-contact materials are subject to Framework Regulation (EC) 1935/2004 and, for plastics, Regulation (EU) 10/2011 (migration limits, positive list of authorized substances), plus the GMP Regulation (EC) 2023/2006 (good manufacturing practice).

Practical assessment for 3D printing

- Layer grooves form microbial niches – cleaning/hygiene problematic.
- Pigments and additives may migrate; conformity must be demonstrated material- and colour-specifically.
- Practical solution: food-safe coating (e.g. epoxy per 10/2011) or silicone moulding.
- Short contact (e.g. cutter) is partly tolerated; continuous use (cup, bottle) not recommended.

Critical point

"Food-safe" is a property to be demonstrated for the specific material in the specific application, not a blanket label. Without conformity evidence, no claim of food suitability.

Class 5 · Toys (children < 14 years)

Legal framework – current status

Toys for children under 14 are subject to EU toy regulation. The new Toy Safety Regulation (EU) 2025/2509 was published on 12 Dec 2025 and entered into force on 1 Jan 2026; it becomes fully applicable from 1 Aug 2030. Until then Toy Safety Directive 2009/48/EC continues to apply. The harmonized EN 71 series remains central to conformity.

Aspect	Directive 2009/48/EC (until 2030)	Regulation 2025/2509 (from 2030)
Legal form	Directive (national transposition)	Regulation (directly applicable)
Chemistry	CMR restrictions	+ endocrine disruptors, PFAS, bisphenols
Documentation	technical file	+ Digital Product Passport (DPP)
Standards	EN 71 series	EN 71 series (extended, e.g. EN 71-20)

Requirements

- CE marking mandatory; EU declaration of conformity.
- EN 71-1 (mechanical/physical), EN 71-2 (flammability), EN 71-3 (migration of elements).
- Risk assessment incl. foreseeable misuse; check small-parts (swallowing).
- Retain technical file for at least 10 years.

Critical point for 3D-printed toys

Swallowable small parts and sharp fracture edges are the most common risks.
Residual monomers (SLA) and pigment migration are chemically critical – complete curing required.
Without EN 71 conformity and CE, no children's toy may be placed on the market.

Class 6 · Medical & Dental

Legal framework

Medical devices are subject to Medical Device Regulation (EU) 2017/745 (MDR). Whether a part is a medical device depends on the intended purpose defined by the manufacturer (diagnosis, therapy, monitoring, etc.). Biocompatibility is assessed per ISO 10993.

Risk classes (MDR, simplified)

Class	Risk	Example	Conformity route
I	low	simple aids (non-sterile/measuring)	self-declaration
IIa	medium	dental models, many splints	notified body
IIb	higher	longer-term application	notified body
III	high	implants	notified body, strictest assessment

Custom-made devices

Products manufactured individually for a specific patient qualify as custom-made devices (MDR Art. 2 No. 3) and follow a dedicated procedure (Art. 52(8), Annex XIII) – typically on medical prescription.

Critical point: positioning decides everything

A dental model without therapeutic purpose may be an aid; a drill guide used on the patient is a medical device.
Healing claims or therapeutic marketing make a product MDR-relevant – regardless of material.
Without approval/validated process and certified resin, no medical application.

Class 7 · Assistive Aids & Orthopaedics

Medical device vs. comfort product

Everyday aids (grip thickeners, opening aids, holders) may be run as comfort/everyday products without therapeutic purpose. As soon as a medical purpose (therapy, correction, relief) is claimed, the MDR applies.

Product	without medical purpose	with medical purpose
cutlery grip thickener	comfort product (GPSR)	aid (MDR poss. Class I)
wrist support	comfort/sport	orthosis (MDR)
insole/splint	–	medical device (MDR)
prosthesis cosmetic cover	cosmetic shell	functional prosthesis (MDR)

Critical point

The boundary runs through the claim, not the appearance. Beware wording such as “relieves”, “corrects”, “therapeutic”.

Always run comfort products with a clear disclaimer (not a medical device).

Class 8 · Machines & Safety Components

Legal framework – current transition

Machines and safety components are subject to Machinery Directive 2006/42/EC until 19 Jan 2027, and bindingly to the new Machinery Regulation (EU) 2023/1230 from 20 Jan 2027. Parallel application is not provided for. The Regulation extends the concept of safety component to software and digital components and introduces cybersecurity requirements.

Aspect	Dir. 2006/42/EC (until 19 Jan 2027)	Reg. 2023/1230 (from 20 Jan 2027)
Legal form	Directive	Regulation (direct)
Safety component	classic mechanical	+ software/digital components
New fields	–	cybersecurity, AI relevance
CE	under Directive	only under Regulation

Critical point for 3D printing

A 3D-printed part used as a safety component of a machine triggers full conformity assessment.
Reproducibility and strength verification are mandatory here (anisotropy!).
Industry 4.0 / networked machines: cybersecurity becomes independently relevant under the new Regulation.

Class 9 · Construction & Architecture

Model vs. construction product

Architectural and urban models are decorative/functional (Class 1–2) and without product-specific regulation. As soon as a part takes on a load-bearing or building-physics function in the structure, the Construction Products Regulation (EU) 305/2011 (CPR) applies with declaration of performance and CE.

Product	Class	Requirement
architectural model (scale)	1–2	none product-specific
urban/terrain model	1–2	none product-specific
decorative facade element	1–2	GPSR
load-bearing/building-physics part	9	CPR 305/2011, CE, declaration of performance

Certifications & Conformity Overview

Mark/standard	What	When relevant
CE	EU conformity marking	toy, machine, medical, construction product
EU declaration of conformity	manufacturer declaration	accompanies CE products
EN 71 (1–3, …)	toy safety	children's toys
ISO 10993	biocompatibility	medical/dental
MDR 2017/745	medical devices	medical intended purpose
EU 10/2011	food-contact plastics	food contact
Machinery Reg. 2023/1230	machine safety	machine/safety component from 2027
CPR 305/2011	construction products	load-bearing/building-physics parts
ISO 9001	quality management	operational, not a product mark

Industry 4.0 and the transition

Industry 4.0 was a transitional term; regulatory development (new Machinery Regulation, AI Act, cybersecurity, Digital Product Passport) shifts the focus from mere connectivity towards conformity of digital and safety-relevant components.

For 3D printing this is currently a peripheral topic but gains importance for networked machines and safety-relevant parts.

General note

This guide describes the general legal framework (as of March 2026) and serves orientation. It is not legal advice and does not replace case-by-case assessment. For regulated applications, expert advice and possibly a notified body must be involved.

References: SICHERHEITSWERK (health/occupational safety), WERKSTOFFWERK (materials engineering), monograph (scientific fundamentals).