Technical file — product with CE marking

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Technical documentation required by the Union harmonisation legislation that applies to the product (Directive 2009/48/EC; part 5). Regulation (EU) 2023/988 applies to this product only for the aspects and risks which that legislation does not cover (Article 2(1)), and its Article 9 does not apply to it (Article 2(1), third subparagraph, point (b)); the structure of Article 9(2) is used here for those remaining risks. The manufacturer completes the file against the annex of the act it applies.

1. Identification

Product	Wooden toy train T1
Brand / trade mark	Example
Manufacturer	Example Trading Co Ltd, 1 Example Road, Shenzhen, China, info@example.com
Markets	Germany, France; online marketplaces

2. General description

Wooden toy train T1: Wooden toy train with a locomotive and two wagons, for play. Materials and components: beech wood, water-based paint. Users: children from 3 years. Power: none.

3. Risk analysis and solutions adopted

Category noted from the product data: product for children under 14.

Hazard	How it arises	Typical measures	Evidence held
Mechanical hazards from design and construction	Sharp edges, points, gaps that can trap fingers, unstable shapes or parts that loosen can injure the user during normal or reasonably foreseeable use.	• Design with rounded edges, closed gaps and a stable base • Typical finishing and assembly checks on each production batch • Warning against the remaining hazard where it cannot be designed out	Design drawings, the manufacturer's own inspection records per batch, and test reports to the standard the manufacturer applied, where held
Hazardous substances in materials and composition	Materials, coatings, dyes or additives that touch the skin or mouth, or release substances during use, can expose the user to harmful substances.	• Choice of materials from suppliers who state their composition • Typical exclusion of materials with known restricted substances • Instruction to ventilate, wash or wear the product only as described, where relevant	Supplier declarations of composition, material specifications and chemical test reports held by the manufacturer

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Hazard	How it arises	Typical measures	Evidence held
Packaging hazards	Plastic bags and film can cause suffocation, and small packaging parts, staples or desiccant sachets can be swallowed, especially by children.	• Packaging film of a size or thickness that typically lowers the suffocation risk, or perforated film • Suffocation and 'do not eat' warnings on the packaging • Removal of loose small packaging parts where possible	Packaging specification, artwork of the warnings and the manufacturer's packaging inspection record
Faulty assembly, installation, use or maintenance	Unclear or missing instructions can lead the consumer to assemble, install, use, clean or maintain the product in a way that makes it unsafe.	• Step-by-step instructions with pictures for assembly and, where applicable, installation • Maintenance and cleaning instructions, including what the consumer must not do • Design that typically allows assembly only in the correct way	The instructions as supplied, with their version, and the record of the manufacturer's own review of them
Effect on other products used with it	Where the product is reasonably foreseeably used with or connected to other products, it can damage them or make them unsafe, for example by overloading, heating or wrong signals.	• Statement in the instructions of the products and connections it is designed for • Design limits on output, load or connection that typically protect connected products • Warning against combinations that are not intended	Compatibility notes, the specifications of the interfaces and any interconnection test reports held by the manufacturer
Effect of other products on it	Accessories, spare parts, chargers, consumables or software from other sources that are reasonably foreseeably used with the product can change how it works and make it unsafe.	• Specification of the accessories, parts and software meant to be used with it • Design that typically rejects or tolerates unsuitable accessories • Warning to use only the specified items	List of specified accessories and parts, supplier declarations for them and the manufacturer's own compatibility checks
Missing or unclear presentation, labelling and warnings	If the labelling, age information, warnings or instructions for safe use and disposal are missing, unclear or not in a language the consumer understands, the consumer may not know how to avoid a hazard.	• Warnings and safe-use instructions on the product, packaging or accompanying document • Age suitability information where relevant • Disposal information and the identification and contact details on the product or packaging	Label and packaging artwork, the instructions as supplied in each language and the record of their review

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Hazard	How it arises	Typical measures	Evidence held
Risks for vulnerable consumers	Children, older people, persons with disabilities, and differences between women and men in body size or strength can make a product that is safe for one user hazardous for another.	• Identification of the intended and reasonably foreseeable users in the risk analysis • Design adjustments such as grip, force, size or readability for those users • Warnings or restrictions on use where a group cannot be protected by design	The manufacturer's risk analysis covering the user groups, and any user or test reports held
Appearance that may lead to unintended use	A product that looks like food, or that looks attractive to children although not meant for them, may be put in the mouth, sucked, swallowed or played with.	• Design that avoids the shape, colour, smell or packaging of food • Design and packaging that do not typically appeal to children where the product is not meant for them • Warnings and placement information such as 'keep out of reach of children'	Design review record and pictures of the product and packaging as placed on the market
Cybersecurity and evolving, learning or predictive functions (where applicable)	Where the product is connected or its behaviour changes through software, updates or learning, external interference, loss of connection or a changed function may affect its safety.	• Security features such as authentication and protected updates, where the nature of the product requires them • Safe state of the product when the connection is lost or an update fails • Review of the safety of each software change before release	Software version records, the manufacturer's security assessment and update test records, where applicable

Product for children under 14

Hazard	How it arises	Typical measures	Evidence held
Choking on small parts	Parts that are small or that detach through biting, pulling or dropping can be swallowed or inhaled by a child.	• Construction without detachable small parts for the youngest age groups • Typical pull, torque and drop checks on parts that a child can grip • Age information and a small-parts warning where the product is not for young children	Test reports to the toy or child-product standard the manufacturer applied, and batch inspection records
Strangulation and entanglement	Cords, straps, loops and ribbons can wrap around a child's neck or trap a limb.	• Limits on cord length and loop size in the design • Break-away fastenings where a cord is needed • Warning and instructions on safe placement	Design drawings with cord and loop dimensions and test reports held by the manufacturer

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Hazard	How it arises	Typical measures	Evidence held
Chemical exposure through mouthing and skin contact	Children typically put products in their mouth and touch them for long periods, so substances in paints, plastics and textiles can be taken up.	• Choice of materials and coatings suitable for children's products • Supplier declarations of composition for each material	Supplier declarations and chemical test reports held by the manufacturer
Sharp edges, points and pinching	Edges, points, hinges and folding mechanisms can cut a child or trap fingers during play or handling.	• Rounded edges and covered points • Gaps in moving parts designed so that fingers are not trapped • Inspection of each batch for burrs and defects	Test reports to the standard the manufacturer applied and batch inspection records
Suffocation and enclosure	Plastic film, bags or enclosed spaces large enough for a child to enter can block breathing.	• Ventilation openings in enclosures and masks • Packaging film that typically lowers the suffocation risk • Suffocation warnings on the packaging	Packaging specification and test reports held by the manufacturer
Battery and magnet ingestion	Button batteries and small strong magnets that a child can reach can cause severe internal injury if swallowed.	• Battery compartments that need a tool or two independent movements to open • Magnets fully enclosed so they cannot come loose • Warnings about the hazard of swallowing batteries and magnets	Design drawings and test reports held by the manufacturer

For each risk the manufacturer keeps the evidence named in part 4 and adds what is specific to this model.

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4. Evidence held by the manufacturer and the outcome of the test reports

File or report	Laboratory	Date	Standard or method	Outcome

For each report of a test conducted by the manufacturer or by another party on its behalf the manufacturer enters here: the laboratory, the date, the standard or method tested and the outcome.

Test reports and certificates are the manufacturer's own, from the laboratory it chose; this file does not replace testing or certification.

5. Union harmonisation legislation and standards applied (as stated by the manufacturer)

Directive 2009/48/EC (toys)

Where a standard or other element has been applied only in part, the manufacturer identifies the parts which have been applied.

The manufacturer keeps this documentation up to date and at the disposal of the market surveillance authorities for the period required by the legislation applied.

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