Technical file

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Technical documentation under Article 9(2) of Regulation (EU) 2023/988: at least a general description of the product and its essential characteristics relevant for assessing its safety and, as appropriate to the possible risks related to the product, an analysis of those risks and the solutions adopted to eliminate or mitigate them, the outcome of any test reports, and the list of the European standards or other elements applied to meet the general safety requirement.

1. Identification

Product	Stainless steel lunch box B1
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

Stainless steel lunch box B1: Lunch box with two compartments and a lid, a food contact material for packed meals. Materials and components: stainless steel 304, silicone seal. Users: adults. Power: none.

3. Risk analysis and solutions adopted

Category noted from the product data: food contact material.

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

Food contact material

Hazard	How it arises	Typical measures	Evidence held
Migration of substances into food	Substances in plastics, coatings, inks, rubber or metals can pass into food, especially with heat, fat or acid.	• Materials suitable for food contact chosen from suppliers who state this • Supplier declarations of compliance for each food contact material • Instruction to wash before first use	Supplier declarations of compliance and migration test reports held by the manufacturer
Use outside the intended conditions	Use in a microwave, oven, dishwasher or with hot, fatty or acidic food beyond what the material is designed for can increase migration or damage the product.	• Clear statement of the intended temperatures and food types • Symbols or text for microwave, oven and dishwasher suitability • Warnings against unsuitable use	Specification of the conditions of use and test reports for those conditions held by the manufacturer

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Hazard	How it arises	Typical measures	Evidence held
Breakage and fragments	Glass, ceramic or brittle plastic can crack or shatter with heat shock or impact and leave fragments in food or cause cuts.	• Material and wall thickness chosen for the intended use • Instructions on temperature changes and handling • Inspection of each batch for cracks and defects	Batch inspection records and test reports held by the manufacturer
Hygiene and cleaning	Shapes that cannot be cleaned well can hold food residues and allow bacteria to grow.	• Design with smooth, reachable surfaces • Parts that can be taken apart for cleaning • Cleaning instructions	Design review record and the instructions as supplied
Missing identification as food contact material	Without the food contact information and instructions, the consumer cannot tell whether and how the product may be used with food.	• Food contact symbol or wording on the product, label or packaging • Instructions for safe use with food • Traceability of each batch to its materials	Label artwork and the batch traceability records held by the manufacturer

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

4. Evidence held by the manufacturer and the outcome of the test reports (Article 9(2)(a))

File or report	Laboratory	Date	Standard or method	Outcome

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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. European standards and other elements applied to meet the general safety requirement (Article 9(2)(b))

— to be entered by the manufacturer

Where a standard or other element has been applied only in part, the manufacturer identifies the parts which have been applied (Article 9(2), third subparagraph).

The manufacturer keeps this documentation up to date and at the disposal of the market surveillance authorities for 10 years after the product has been placed on the market, and makes it available to those authorities upon request (Article 9(3)).