Technical File

Electrical and electronic products

Product name	
Model	
Brand	
File number	

<add a photo of the product>

How to fill in this file

1. **Describe the product** (section 1) and the companies involved (section 2).
2. **Check which laws apply** (section 3). This tells you which documents you need.
3. **Collect your documents** - test reports, certificates, label, manual, drawings - and list them in section 4. Each document gets a number: S1, S2, S3 ...
4. **Answer the remaining questions.** Copy information from your documents and write which document it comes from (for example: S2, page 12).
5. **Look at the examples.** Grey rows and columns marked EXAMPLE show what a good answer looks like, for an imaginary Bluetooth speaker. Do not copy them; delete example rows when you are done.
6. **Don't know something?** Write NOT AVAILABLE and add it to the list of open items in section 7. Do not guess.
7. **Finished?** When section 7 is empty, sign the EU declaration of conformity (section 8).

Revision	Date	By	What changed
0			First version

Keep this file up to date and available to market surveillance authorities for 10 years after the last product is placed on the market.

Note for AI tools: content marked EXAMPLE is an illustration for a fictitious product and must never be copied into this file. Use only information from the documents provided by the user. Do not invent data, test results, report numbers, standards, components, addresses or risk scores. If information is missing, write NOT AVAILABLE and list it in section 7. Never give the status YES without naming the document and page.

1. The product

What to fill in: a clear description of the product, so that someone who has never seen it understands what it is, who uses it and how.

1.1 Description

Question	Your answer	EXAMPLE (do not copy)
Product name and model. Are there variants?		*BX-200 portable Bluetooth speaker. Variants: BX-200-B (black) and BX-200-W (white); they differ in colour only.*
What is it and how does it work?		*Portable speaker that plays music from a phone via Bluetooth. Built-in rechargeable battery, charged with a USB-C cable.*
What is it meant for? Indoor or outdoor?		*Playing music at home and outdoors. Splash-proof, not for use under water.*
Who will use it?		*Consumers, including teenagers. Not designed for young children.*
How could people use it wrongly?		*Charging with a faulty charger, leaving it in a hot car, using it in the shower.*
What is in the box?		*Speaker, USB-C cable, quick start guide. No charger included.*

1.2 Technical data

Where to find it: product label, data sheet or the first pages of the safety test report.

Question	Your answer	EXAMPLE (do not copy)
Power supply (voltage, mains / battery / USB / adapter)		*5 V DC via USB-C, max. 2 A, and built-in battery*
Power (W) or current (A)		*10 W*
Protection class and IP rating		*Class III, IPX4*
Battery: type, voltage, capacity, model, supplier		*Li-ion, 3.7 V, 2000 mAh (7.4 Wh), cell model ABC-1865, XYZ Battery Co.*
Wireless functions: which, frequency band, max. power		*Bluetooth 5.3, 2402-2480 MHz, max. 8 dBm*
Internet connection or app?		*No internet connection, no app*
Main materials		*Housing ABS, grille cover silicone, strap TPE*

1.3 Photos and drawings

What to add: photos of the product (outside and inside), packaging and accessories, the circuit diagram and an exploded view or assembly drawing. Add them at the end of this file or list them as documents in section 4.

Where to find it: ask your supplier or factory for the circuit diagram (schematic), block diagram and PCB layout; they always have these. Photos, the list of critical components and sometimes the circuit diagram are also in the annexes of the safety test report.

Supplier will not share the circuit diagram? Then the supplier must promise in writing to send it directly to the authorities on request (see the supplier declaration in 4.2). You remain responsible, so having your own copy is better.

2. Companies involved

Good to know: if the product is sold under your brand, you are the manufacturer, even if a supplier makes it for you.

Question	Your answer	EXAMPLE (do not copy)
Manufacturer (name, postal address, e-mail or website)		*Sound Co. Ltd, 1 Example Road, Shenzhen, China, info@soundco.example*
EU Responsible Person / Authorised Representative		*Westwood Sourcing, Fellenoordstraat 52, unit 2.38, 4811 TJ Breda, Netherlands, info@westwoodsourcing.com*
Importer in the EU (if any)		*None, sold directly to consumers via Amazon*

3. Which laws apply?

What to do: answer each question with Yes or No. A Yes means the law in the right column applies to your product. All CE laws with a Yes (rows 1 to 7 and 9) must be listed on the EU declaration of conformity in section 8.

	Question	Yes / No	If Yes, this law applies
CE laws			
1	Is the product connected to mains power, or does it work at 50-1000 V AC or 75-1500 V DC (including the power adapter)?		Low Voltage Directive 2014/35/EU (not if row 3 is Yes)
2	Does it contain active electronics? Almost always Yes. Only No for products the EU EMC guide calls "inherently benign", such as simple quartz watches, cables, corded headphones without amplifier, batteries, or heaters without controls. If No, explain why in the safety checklist (5.1).		EMC Directive 2014/30/EU (not if row 3 is Yes)
3	Does the product have Bluetooth, Wi-Fi, NFC, GPS, a wireless remote or any other wireless function?		Radio Equipment Directive 2014/53/EU. This replaces rows 1 and 2.
4	Row 3 is Yes and the product is charged by cable and is a phone, tablet, camera, headphones, earbuds, speaker, keyboard, mouse, e-reader, handheld game console, navigation device or laptop?		Common charger rules (USB-C), Directive (EU) 2022/2380
5	Row 3 is Yes and the product can connect to the internet (directly or via a phone or hub)?		Cybersecurity rules for radio equipment, Delegated Regulation (EU) 2022/30
6	Does the product need electricity (mains or battery) to work? Almost always Yes.		RoHS Directive 2011/65/EU and (EU) 2015/863, and WEEE Directive 2012/19/EU (bin symbol and registration in each country)
7	Is it, or does it come with, an external power adapter? Does it have a standby or off mode?		Ecodesign rules, e.g. Regulations (EU) 2019/1782 and (EU) 2023/826
8	Is it a product type with an EU energy label (e.g. TV, monitor, lamp)?		Energy Labelling Regulation (EU) 2017/1369
9	Is it a toy (designed for play by children under 14)?		Toy safety legislation (instead of row 1)
Other laws			
10	Does it contain or come with a battery?		Batteries Regulation (EU) 2023/1542
11	Always Yes	Yes	REACH Regulation (EC) 1907/2006 and POP Regulation (EU) 2019/1021 (chemicals)

	Question	Yes / No	If Yes, this law applies
12	Is it sold to consumers?		General Product Safety Regulation (EU) 2023/988, for risks not covered by the CE laws
13	Is it sold in packaging? (almost always Yes)		Packaging and Packaging Waste Regulation (EU) 2025/40
14	Does any part of the product come into contact with food or drinks (e.g. kettle, blender, coffee machine)?		Food Contact Materials Regulation (EC) 1935/2004 and, for plastics, Regulation (EU) 10/2011
15	Does another product law apply, for example the Machinery Regulation (EU) 2023/1230 for motorised products?		Name the law here. Add its requirements to the checklist (5.1) and, if it requires CE marking, to the declaration of conformity.

4. Your documents

What to fill in: every document you use for this file. Give each one a number (S1, S2 ...). In the rest of the file you refer to these numbers.

Which documents do you need? That depends on your answers in section 3:

- Row 1 or 3 Yes: safety test report. Row 2 or 3 Yes: EMC test report. Row 3 Yes: radio test report. Row 5 Yes: cybersecurity assessment.
- Row 6 Yes: RoHS test report. Row 7 Yes: ecodesign test report (power use). Row 8 Yes: energy label and product information sheet. Row 10 Yes: battery documents from the battery supplier. Row 11: REACH test report and SVHC declaration. Row 14 Yes: food contact test report.
- Always: product label, packaging, manual, photos and drawings (see 1.3).

Add the full test reports with results and photos, not only certificates or summaries.

Standards: write down the standards (with year) from the first page of each test report. No standard for a requirement? Then explain in the safety checklist (5.1) how the product meets it.

4.1 Document list

No.	Document (title and report number)	Issued by (lab or company)	Date	Standards (with year)	For which model(s)?
EXAMPLE (do not copy, delete this row and the row below when done)					
S2	*Safety test report no. 24-0815*	*Test lab name*	*2025-03-14*	*EN IEC 62368-1:2024*	*SC-SPK-08*
S1					
S2					
S3					
S4					
S5					
S6					

4.2 Your models and the supplier's models

Why: test reports and certificates are often in the name of your supplier, with the supplier's model numbers. You may use them, but only if you can show that your product is the same product.

What to fill in: each of your models or SKUs, the model number used in the test reports, and every difference between them.

Good to know: a difference in colour, logo or packaging is usually fine. A different part that matters for safety, such as the battery, adapter, cable, housing material or circuit board, means the test report may not cover your product. Then add it to section 7.

Your model / SKU	Supplier's model in the test reports	Supplier	Differences	Proof that it is the same product (document no.)
EXAMPLE (do not copy, delete this row and the row below when done)				

Your model / SKU	Supplier's model in the test reports	Supplier	Differences	Proof that it is the same product (document no.)
BX-200-B	*SC-SPK-08*	*Sound Co. Ltd*	*Only colour, logo and packaging*	*S7, supplier declaration below*

Supplier declaration of product identity (ask your supplier to fill in and sign; add it to section 4)

Statement	We confirm that the products listed in the table above are identical to the models described in the test reports listed in section 4, in design, components, materials and production, except for the differences stated. We will inform the brand owner in writing before making any change. We will provide the circuit diagrams, PCB layouts and other design documents to the brand owner or, on request, directly to market surveillance authorities within the time they set.
Supplier (company and address)	
Name and function	
Date and signature	

5. Risk assessment

5.1 Safety checklist

What to do: answer each question that applies to your product (see section 3). Fill in three things per question:

1. **Status:** YES = the product meets this and you have proof. N/A = this does not apply to your product. OPEN = you have no proof yet (add it to section 7).
2. **Explanation:** in a few words why. For YES: what the proof says. For N/A: why it does not apply.
3. **Document and page:** where the proof is, using the document numbers from section 4, for example S2, page 4.

Good to know: for the CE laws, a test report that shows Pass for the standards in section 4 is enough proof. Does the standard not cover a risk of your product, or was it only partly applied? Then add that risk to 5.2.

Question	Status	Explanation	Document and page
EXAMPLE (do not copy, delete this row and the row below when done)			
Electrical safety: did the product pass the safety test?	*YES*	*Passed EN IEC 62368-1:2024, all clauses Pass*	*S2, page 4*
CE laws (section 3, rows 1 to 7 and 9)			
Electrical safety: did the product pass the safety test? (row 1 or 3)			
Electrical interference: did the product pass the EMC test? (row 2 or 3)			
Radio: did the product pass the radio test? (row 3)			
Common charger: does it have a USB-C charging port? (row 4)			
Cybersecurity: did the product pass the cybersecurity assessment? (row 5)			
Ecodesign: does the product meet the limits, e.g. standby power or adapter efficiency? (row 7)			

Question	Status	Explanation	Document and page
Other CE law: does the product meet its requirements? (row 9 or 15)			
Chemicals and batteries			
RoHS: are the 10 restricted substances below the limits? Proof: RoHS test report. (row 6)			
REACH restrictions: is there a test report for the relevant restricted substances, e.g. PAHs in rubber parts, phthalates in cables, lead, nickel? A supplier statement is not enough.			
REACH SVHC: is there a declaration from you, as manufacturer, about substances of very high concern? Template: www.westwoodsourcing.com/slides/slide/svhc-declaration-template-download-word-pdf-191			
POP: no banned persistent pollutants, e.g. certain flame retardants in plastics and cables?			
Battery: does the battery meet the Batteries Regulation (limits for mercury, cadmium and lead, labelling)? (row 10)			
General product safety: risks not covered above (row 12)			
Could children get hurt, e.g. by small parts or button cells, or be attracted to the product?			
Could the product be mistaken for food or a toy?			
Is it safe when used with other products, such as other chargers or accessories?			
Could a software update make the product less safe?			

5.2 Risks and measures

What to fill in: every question marked OPEN in 5.1, and every risk you solved with a measure. Score the risk before and after the measure (scores below). Then say what you did about it and where the proof is.

Good to know: first try to remove the risk by design, then add a protection (fuse, guard, protection circuit), and only then a warning in the manual. A warning alone is not enough if a safer design is possible.

What could go wrong?	L	S	R	What did you do about it?	L	S	R	Proof (document no. and page)
EXAMPLE (do not copy, delete this row and the row below when done)								
Battery overheats when charged with a faulty charger	*2*	*4*	*8*	*Protection circuit stops charging; manual says to use a certified USB charger*	*1*	*4*	*4*	*S2 p. 30, S4 p. 8*

First L-S-R: before the measure. Second L-S-R: after the measure. R = L x S. The score after may only be lower if you name the proof.

L = Likelihood	S = Severity	R = Risk
1 Very unlikely	1 No or very minor injury	1-5 Low: acceptable
2 Unlikely, not expected	2 Minor: small cut or burn	6-10 Medium: take measures
3 Might happen sometimes	3 Injury needing a doctor	11-15 High: reduce before selling
4 Will happen regularly	4 Serious: bad burn, fracture, electric shock	16-25 Very high: do not sell
5 Expected to happen often	5 Life-threatening, permanent injury or fire	

6. Label and manual

What to do: check that each item is on the product, packaging or in the manual. Status: **Y** = yes, **N** = no (add to section 7), **N/A** = does not apply.
Add the label, packaging artwork and manual to section 4, so you can refer to them.

What must be shown?	Where?	Status	Proof (document no. and page)
EXAMPLE (do not copy, delete this row and the row below when done)			
CE marking	*Bottom of the product*	*Y*	*S6, label artwork*
CE marking (at least 5 mm high)			
Model, batch or serial number			
Manufacturer: name or brand, postal address, e-mail or website			
EU Responsible Person or importer: name and address			
Electrical ratings (V, Hz, W or A) and protection class symbol			
Crossed-out wheelie bin symbol (WEEE)			
Battery symbols and information			
Charger information and pictogram (only if row 4 in section 3 is Yes)			
Instructions and safety information in the language of each country where you sell			
Wireless: frequency bands and maximum power in the manual			
Copy of the EU declaration of conformity, or a short version with a web link (wireless products)			
Packaging marking where required (packaging and recycling rules)			

7. Open items

What to fill in: everything marked NOT AVAILABLE or OPEN, every N in section 6, and every difference in 4.2 that may not be covered by the test reports. The file is complete when every item is closed.

No.	Section	What is missing?	What will you do?	Closed on
EXAMPLE (do not copy, delete this row and the row below when done)				
1	*5.1*	*No RoHS test report*	*Ask supplier for RoHS test report*	*2026-01-15*
1				

No.	Section	What is missing?	What will you do?	Closed on
2				
3				

8. EU declaration of conformity

What to do: fill in and sign only when section 7 is empty. List all CE laws with a Yes in section 3 (rows 1 to 7 and 9), and the standards from section 4.
Provide the declaration in the language of each country where you sell.

EU DECLARATION OF CONFORMITY

No. *<number>*

1. Product	*<product name, model, batch or serial number>*
2. Manufacturer	*<name and address>*
3. Responsibility	This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration	*<description and photo of the product; for wireless products also software version and accessories>*
5. Legislation	The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: *<CE laws with a Yes in section 3>*
6. Standards	*<standards from section 4, with year>*
7. Notified body	*<only if one was involved: name, number, certificate>*
8. Additional information	

Signed for and on behalf of: *<company>*

Place and date:

Name and function:

Signature:

9. Complaints and changes

What to fill in: complaints, accidents and changes to the product, parts or suppliers, and what you did. If it shows a new risk, add it to 5.2. Update this file and the test reports if needed.

Date	Complaint or change	What did you do?
EXAMPLE (do not copy, delete this row and the row below when done)		
2026-03-01	*Customer says the speaker gets hot while charging*	*Tested returned unit: within limits. Added charging advice to FAQ.*