EU Market Access Assessment

Regulatory Assessment Report

Identify applicable EU product regulations, required compliance evidence and the next steps to bring your product to the EU market.

Case	Assessment date	Issued on
Synthetic sample case – Lumenwerk TL-230 (not officially issued)	2026-10-30	2026-10-30

Regulatory product profile

Synthetic sample report, not officially issued. Fictional product and manufacturer data; evidence not independently verified. Product, market and event information as reported; legal decisions are stated separately.

Subject / requirement	Status
Assessed product	Lumenwerk TL-230
Reported EU target markets	Germany, Austria
Reported first EU placing of the unit	Lumenwerk GmbH: 2026-10-29

Summary

> **Partially determined**

LVD: 8 statutory duties were established for Lumenwerk TL-230 for Lumenwerk GmbH. In particular review conformity assessment, technical documentation, EU declaration of conformity and CE marking; not a blanket market approval. Further separate review needed (all open routes): EMV, REACH, WEEE, RoHS, ESPR.

This assessment is limited to the source-bound decision paths that could be evaluated. Requirements outside those paths are neither confirmed nor excluded.

Next steps

1. **Implement and evidence the duty: CE marking under Articles 16–17** · Priority: High
2. **Create a substance and use inventory** · Priority: High
3. **Clarify the REACH activity link** · Priority: High
4. **Document target Member States and supply of the electrical equipment** · Priority: High
5. **Clarify the operator role from its activities** · Priority: High

Actions and closure criteria in detail

Implement and evidence the duty: CE marking under Articles 16–17

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
Verify and document implementation of the established duty: CE marking under Articles 16–17. Statutory documents or procedures: EU declaration of conformity under Article 15 and Annex IV; Conformity assessment: Internal production control (Module A) under Annex III.
Assessment reference: Directive 2014/35/EU: Arts. 16–17; Directive 2014/35/EU: Art. 2(3); Art. 6; Directive 2014/35/EU: Art. 6(2); Annex III; Directive 2014/35/EU: Art. 6(2); Annex III §2

Closure criterion: Implementation of the identified duty is evidenced for the stated object and role; required documents/procedures are reconciled. Documents you marked as available are not independently verified without substantive review.

Create a substance and use inventory

Priority: High

Lumenwerk TL-230
First record substances, affected constituent articles, uses, supplier evidence and inventory date; explicitly flag unknown substances. A customer statement establishes neither REACH applicability nor SCIP duties.
Assessment reference: Regulation (EC) No 1907/2006: Art. 58(1)(c); Annex XIV; Regulation (EC) No 1907/2006: Art. 59; Annex XIV; Annex XVII

Closure criterion: A dated, item-specific substance/use inventory is reconciled against evidence and outstanding uncertainties are recorded.

Clarify the REACH activity link

Priority: High

Lumenwerk TL-230
For this product and operator, clarify whether the relevant REACH activity takes place within the EU/EEA legal system. Record the specific activity and responsible operator.
Assessment reference: Regulation (EC) No 1907/2006: Art. 1-3

Closure criterion: The relevant activity and associated operator are recorded for this product in the case.

Document target Member States and supply of the electrical equipment

Priority: High

Lumenwerk TL-230
Record the Member States in which this specific electrical equipment is placed on the market or made available, the economic operators concerned, and the relevant dates and supply events. Link available records. This information supports a subsequent source-bound review of potential WEEE duties; it does not itself establish registration or applicability.
Assessment reference: Directive 2012/19/EU: Art. 3(1)(j)-(k), Art. 16-18

Closure criterion: The target Member States, responsible operators, placing/supply events and dated evidence are recorded for this specific equipment. WEEE applicability and registration remain subject to a separate qualified legal assessment.

Clarify the operator role from its activities

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
To determine the economic operator role, clarify these facts:
1. Is the assessed economic operator established in the EU?
2. Does the assessed product originate from a third country?
3. Does this economic operator first place the specific product on the EU market?
Assessment reference: Directive 2014/35/EU: Art. 2(5); Art. 8

Closure criterion: The activity questions above are answered for this operator and product and saved in the case.

Is an authorised representative established in the Union appointed under a written mandate?

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
Clarify whether an EU-established authorised representative has a written mandate for this product, and record the representative and the scope of that mandate.
Assessment reference: Directive 2014/35/EU: Art. 7

Closure criterion: Record the representative, the written mandate and its scope, or document that no representative is appointed.

Does an importer or distributor place this electrical equipment on the market under its own name or trademark?

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
Determine whether the importer or distributor places this particular electrical equipment on the EU market under its own name or trademark. Record the operator identity and the actual branding/placing activity.
Assessment reference: Directive 2014/35/EU: Art. 10

Closure criterion: The actual operator, brand and placing-on-market arrangement are documented for this equipment.

In which Member States will this electrical equipment be made available, and which understandable language versions of the instructions, safety information and EU declaration of conformity are required there?

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
List each intended EU Member State and establish which language versions of the instructions, safety information and EU declaration of conformity are required in the relevant market. Retain the supporting market-specific language assessment.
Assessment reference: Directive 2014/35/EU: Art. 6(7), Art. 8(4), Art. 9(2), Art. 15(2)

Closure criterion: Target Member States and the applicable document-language requirements are documented with appropriate sources for this equipment.

Implement and evidence the duty: Product and economic-operator identification and traceability

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
Verify and document implementation of the established duty: Product and economic-operator identification and traceability.
Assessment reference: Directive 2014/35/EU: Art. 6(5)–(6); Art. 8(3); Art. 9(2); Directive 2014/35/EU: Art. 2(3); Art. 6; Directive 2014/35/EU: Art. 6(2); Annex III; Directive 2014/35/EU: Art. 6(2); Annex III §2

Closure criterion: Implementation of the identified duty is evidenced for the stated object and role; required documents/procedures are reconciled. Documents you marked as available are not independently verified without substantive review.

Implement and evidence the duty: Instructions and safety information in the required language

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
Verify and document implementation of the established duty: Instructions and safety information in the required language.
Assessment reference: Directive 2014/35/EU: Art. 6(7); Art. 8(4); Art. 9(2); Directive 2014/35/EU: Art. 2(3); Art. 6; Directive 2014/35/EU: Art. 6(2); Annex III; Directive 2014/35/EU: Art. 6(2); Annex III §2

Closure criterion: Implementation of the identified duty is evidenced for the stated object and role; required documents/procedures are reconciled. Documents you marked as available are not independently verified without substantive review.

Implement and evidence the duty: Ten-year availability of the EU declaration and technical documentation

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
Verify and document implementation of the established duty: Ten-year availability of the EU declaration and technical documentation. Statutory documents or procedures: EU declaration of conformity under Article 15 and Annex IV; Technical documentation demonstrating conformity under Annex III.
Assessment reference: Directive 2014/35/EU: Art. 6(3); Art. 7(2)(a); Art. 8(7); Directive 2014/35/EU: Art. 2(3); Art. 6; Directive 2014/35/EU: Art. 6(2); Annex III; Directive 2014/35/EU: Art. 6(2); Annex III §2

Closure criterion: Implementation of the identified duty is evidenced for the stated object and role; required documents/procedures are reconciled. Documents you marked as available are not independently verified without substantive review.

Implement and evidence the duty: Annex I: Protection against hazards caused by external influences

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
Verify and document implementation of the established duty: Annex I: Protection against hazards caused by external influences.
Assessment reference: Directive 2014/35/EU: Art. 3; Annex I §3; Directive 2014/35/EU: Art. 3; Annex I §1

Closure criterion: Implementation of the identified duty is evidenced for the stated object and role; required documents/procedures are reconciled. Documents you marked as available are not independently verified without substantive review.

Implement and evidence the duty: Annex I: General conditions and safe-use information

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
Verify and document implementation of the established duty: Annex I: General conditions and safe-use information.
Assessment reference: Directive 2014/35/EU: Art. 3; Annex I §1; Directive 2014/35/EU: Art. 3; Annex I §2

Closure criterion: Implementation of the identified duty is evidenced for the stated object and role; required documents/procedures are reconciled. Documents you marked as available are not independently verified without substantive review.

Implement and evidence the duty: Annex I: Protection against hazards from electrical equipment

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
Verify and document implementation of the established duty: Annex I: Protection against hazards from electrical equipment.
Assessment reference: Directive 2014/35/EU: Art. 3; Annex I §2; Directive 2014/35/EU: Art. 3; Annex I §1

Closure criterion: Implementation of the identified duty is evidenced for the stated object and role; required documents/procedures are reconciled. Documents you marked as available are not independently verified without substantive review.

Implement and evidence the duty: Identify supplying and supplied economic operators under Article 11

Priority: High

Lumenwerk TL-230 · Lumenwerk GmbH
Verify and document implementation of the established duty: Identify supplying and supplied economic operators under Article 11.
Assessment reference: Directive 2014/35/EU: Art. 11; Directive 2014/35/EU: Art. 2(3); Art. 6; Directive 2014/35/EU: Art. 6(2); Annex III; Directive 2014/35/EU: Art. 6(2); Annex III §2

Closure criterion: Implementation of the identified duty is evidenced for the stated object and role; required documents/procedures are reconciled. Documents you marked as available are not independently verified without substantive review.

Clarify the Annex XIV date state

Priority: Medium

Lumenwerk TL-230
After recording the substance/use inventory: Review substances, uses and legally effective dates against current official Annex XIV sources.
Assessment reference: Regulation (EC) No 1907/2006: Art. 58(1)(c); Annex XIV

Closure criterion: The substances and uses, and where applicable the Annex XIV entry and dates, are recorded; if no such substance was identified within the documented scope, the review scope, basis and date are recorded. This does not predetermine the legal assessment.

Check current substance-list status

Priority: Medium

Lumenwerk TL-230
After recording the substance/use inventory: Check Candidate List, Annex XIV and Annex XVII against dated official sources for the identified substances.
Assessment reference: Regulation (EC) No 1907/2006: Art. 59; Annex XIV; Annex XVII

Closure criterion: For identified substances, list status, source, date and any changes are recorded; if no relevant substance was identified within the documented scope, the review scope, basis and date are recorded. This documents fact gathering, not a legal exclusion.

EMC: establish emissions and immunity characteristics

Priority: Medium

Lumenwerk TL-230
Document electrical functions, integration configuration, intended use and relevant electromagnetic interference. Provide technical records to establish EMC scope and possible sectoral exclusions.

Closure criterion: The product and market facts are recorded for this item; the legal scope is qualified against the appropriate source or explicitly left unresolved with reasons.

WEEE: establish EEE category and end-of-life route

Priority: Medium

Lumenwerk TL-230
Establish whether the item is electrical or electronic equipment, the relevant equipment category, intended use and end-of-life route, and the first supplier in each target market. Provide product and distribution records.

Closure criterion: The product and market facts are recorded for this item; the legal scope is qualified against the appropriate source or explicitly left unresolved with reasons.

RoHS: establish EEE scope and specific exclusions

Priority: Medium

Lumenwerk TL-230 · Lumenwerk GmbH
Describe the electrical functions, affected assemblies and intended uses. Using technical records, establish whether RoHS covers the equipment and whether any specific exclusions require evidence. This initial step does not establish substance-limit compliance.

Closure criterion: The product and market facts are recorded for this item; the legal scope is qualified against the appropriate source or explicitly left unresolved with reasons.

ESPR: establish product group and applicable measure

Priority: Medium

Lumenwerk TL-230 · Lumenwerk GmbH
Record product category, intended use, regulated sub-items and market date. Then check against legal sources whether an Article 1(2) exclusion or relevant product-specific measure applies; the framework regulation alone does not establish a DPP duty.

Closure criterion: The product and market facts are recorded for this item; the legal scope is qualified against the appropriate source or explicitly left unresolved with reasons.

Statutory duties

Subject / requirement	Status	Basis
Lumenwerk TL-230 — Lumenwerk GmbH — CE marking under Articles 16–17	Established from source	Directive 2014/35/EU: Arts. 16–17; Directive 2014/35/EU: Art. 2(3); Art. 6; Directive 2014/35/EU: Art. 6(2); Annex III; Directive 2014/35/EU: Art. 6(2); Annex III §2
Lumenwerk TL-230 — Lumenwerk GmbH — Product and economic-operator identification and traceability	Established from source	Directive 2014/35/EU: Art. 6(5)–(6); Art. 8(3); Art. 9(2); Directive 2014/35/EU: Art. 2(3); Art. 6; Directive 2014/35/EU: Art. 6(2); Annex III; Directive 2014/35/EU: Art. 6(2); Annex III §2
Lumenwerk TL-230 — Lumenwerk GmbH — Instructions and safety information in the required language	Established from source	Directive 2014/35/EU: Art. 6(7); Art. 8(4); Art. 9(2); Directive 2014/35/EU: Art. 2(3); Art. 6; Directive 2014/35/EU: Art. 6(2); Annex III; Directive 2014/35/EU: Art. 6(2); Annex III §2
Lumenwerk TL-230 — Lumenwerk GmbH — Ten-year availability of the EU declaration and technical documentation	Established from source	Directive 2014/35/EU: Art. 6(3); Art. 7(2)(a); Art. 8(7); Directive 2014/35/EU: Art. 2(3); Art. 6; Directive 2014/35/EU: Art. 6(2); Annex III; Directive 2014/35/EU: Art. 6(2); Annex III §2
Lumenwerk TL-230 — Lumenwerk GmbH — Annex I: Protection against hazards caused by external influences	Established from source	Directive 2014/35/EU: Art. 3; Annex I §3; Directive 2014/35/EU: Art. 3; Annex I §1
Lumenwerk TL-230 — Lumenwerk GmbH — Annex I: General conditions and safe-use information	Established from source	Directive 2014/35/EU: Art. 3; Annex I §1; Directive 2014/35/EU: Art. 3; Annex I §2

Subject / requirement	Status	Basis
Lumenwerk TL-230 — Lumenwerk GmbH — Annex I: Protection against hazards from electrical equipment	Established from source	Directive 2014/35/EU: Art. 3; Annex I §2; Directive 2014/35/EU: Art. 3; Annex I §1
Lumenwerk TL-230 — Lumenwerk GmbH — Identify supplying and supplied economic operators under Article 11	Established from source	Directive 2014/35/EU: Art. 11; Directive 2014/35/EU: Art. 2(3); Art. 6; Directive 2014/35/EU: Art. 6(2); Annex III; Directive 2014/35/EU: Art. 6(2); Annex III §2

Additional reported case and operator facts

Fact	Customer-reported information
General reported product date – not proof of first placing	2026-10-29
Reported operator event	Lumenwerk GmbH: First placing on the market · 2026-10-29 · Market: European Union
Recorded operators	Lumenwerk GmbH

Regulatory acts and applicability status

Assessed object	EU legal regime	Result and next review
Lumenwerk TL-230	EMC Directive 2014/30/EU	Applicability unresolved — Clarify case facts and legal sources
Lumenwerk TL-230	REACH Regulation (EC) No 1907/2006	Applicability unresolved — Clarify case facts and legal sources
Lumenwerk TL-230	WEEE Directive 2012/19/EU	Applicability unresolved — Clarify case facts and legal sources
Lumenwerk TL-230 — Lumenwerk GmbH	Low Voltage Directive 2014/35/EU	Individual duties triggered; no conformity conclusion
Lumenwerk TL-230 — Lumenwerk GmbH	RoHS Directive 2011/65/EU	Applicability unresolved — Clarify case facts and legal sources
Lumenwerk TL-230 — Lumenwerk GmbH	Ecodesign for Sustainable Products Regulation (EU) 2024/1781	Applicability unresolved — ESPR entry and legal source still require qualification; no duty established.

Evidence status based on your responses

Your item / document	Status based on your responses	Verification status
Lumenwerk TL-230 — EU DoC	Reported as partially available	Customer-reported only, not confirmation of compliance

SOLL / reported-status reconciliation: review outstanding

Statutory item	Assessed object	Reported link	Required evidence action
EU declaration of conformity under Article 15 and Annex IV	Lumenwerk TL-230	Not explicitly linked; unverified	Link any available item/procedure to the specific object and duty, then substantively review its current status and content.

Statutory item	Assessed object	Reported link	Required evidence action
Conformity assessment: Internal production control (Module A) under Annex III	Lumenwerk TL-230	Not explicitly linked; unverified	Link any available item/procedure to the specific object and duty, then substantively review its current status and content.
EU declaration of conformity under Article 15 and Annex IV	Lumenwerk TL-230	Not explicitly linked; unverified	Link any available item/procedure to the specific object and duty, then substantively review its current status and content.
Technical documentation demonstrating conformity under Annex III	Lumenwerk TL-230	Not explicitly linked; unverified	Link any available item/procedure to the specific object and duty, then substantively review its current status and content.

Open date and transition predicates

Item	Regulatory area	Next verification
Lumenwerk TL-230	REACH Regulation (EC) No 1907/2006	Resolve case-specific event and legal-effective dates and any transitional/deadline predicates from an official source.

Required documents and procedures

Regulatory product profile	Statutory duties	Required documents and procedures	Legal sources
Lumenwerk TL-230 — Lumenwerk GmbH	CE marking under Articles 16–17	EU declaration of conformity under Article 15 and Annex IV	Directive 2014/35/EU: Art. 15; Annex IV
Lumenwerk TL-230 — Lumenwerk GmbH	CE marking under Articles 16–17	Procedure: Conformity assessment: Internal production control (Module A) under Annex III	Directive 2014/35/EU: Art. 6(2); Annex III
Lumenwerk TL-230 — Lumenwerk GmbH	Ten-year availability of the EU declaration and technical documentation	EU declaration of conformity under Article 15 and Annex IV	Directive 2014/35/EU: Art. 15; Annex IV
Lumenwerk TL-230 — Lumenwerk GmbH	Ten-year availability of the EU declaration and technical documentation	Technical documentation demonstrating conformity under Annex III	Directive 2014/35/EU: Art. 6(2); Annex III §2

Statutory retention period – case-specific dates

Product and role	Deadline and evidence boundary	Legal basis
Lumenwerk TL-230 — Lumenwerk GmbH	The statutory retention period is ten years after actual first EU placing; the unit-specific placing date or relevant historical legal source still needs evidence. No calendar deadline has been calculated.	Directive 2014/35/EU: Art. 6(3)

Additional context of the assessment outcome

The following individual statutory duties have been established for the identified objects from the referenced sources. Still to clarify: Implement and evidence the duty: CE marking under Articles 16–17; Create a substance and use inventory; Clarify the REACH activity link.

Legal sources

Source	Reference	Source date
Directive 2014/35/EU	Arts. 16–17	2026-10-05
Directive 2014/35/EU	Art. 2(3); Art. 6	2026-10-05
Directive 2014/35/EU	Art. 6(2); Annex III	2026-10-05
Directive 2014/35/EU	Art. 6(2); Annex III §2	2026-10-05
Directive 2014/35/EU	Art. 15; Annex IV	2026-10-29
Directive 2014/35/EU	Art. 6(5)–(6); Art. 8(3); Art. 9(2)	2026-10-05
Directive 2014/35/EU	Art. 6(7); Art. 8(4); Art. 9(2)	2026-10-05
Directive 2014/35/EU	Art. 6(3); Art. 7(2)(a); Art. 8(7)	2026-10-05
Directive 2014/35/EU	Art. 3; Annex I §3	2026-10-05
Directive 2014/35/EU	Art. 3; Annex I §1	2026-10-05
Directive 2014/35/EU	Art. 3; Annex I §2	2026-10-05
Directive 2014/35/EU	Art. 11	2026-10-05
Regulation (EC) No 1907/2006	Art. 58(1)(c); Annex XIV	2026-10-05
Regulation (EC) No 1907/2006	Art. 59; Annex XIV; Annex XVII	2026-10-05
Regulation (EC) No 1907/2006	Art. 1-3	2026-10-05
Directive 2012/19/EU	Art. 3(1)(j)-(k), Art. 16-18	2026-10-05
Directive 2014/35/EU	Art. 2(5); Art. 8	2026-10-05
Directive 2014/35/EU	Art. 7	2026-10-05
Directive 2014/35/EU	Art. 10	2026-10-05
Directive 2014/35/EU	Art. 6(7), Art. 8(4), Art. 9(2), Art. 15(2)	2026-10-05
Directive 2014/35/EU	Art. 6(3)	2026-10-29

Source date: 2026-10-29

Limitations

Synthetic and not officially issued sample. This sample is not an official Model C issuance and has no valid report reference.

The assessment is neither a conformity certificate nor an official market authorisation.

Customer implementation and document quality were not materially assessed.

SYNTHETIC SAMPLE · NOT OFFICIALLY ISSUED