



C/2025/1758

31.3.2025

Judgment of the General Court of 12 February 2025 – Klein v Commission

(Case T-394/23) ⁽¹⁾

(Public health – EU regulatory framework governing medical devices – Safeguard clause – Article 8(1) and (2) of Directive 93/42/EEC – Notification by a Member State of a decision prohibiting the placing on the market of a medical device – Medical device Inhaler Broncho-Air® – Repeal of Directive 93/42 – Articles 94 to 97 of Regulation (EU) 2017/745 – Infringement of essential procedural requirements)

(C/2025/1758)

Language of the case: German

Parties

Applicant: Christoph Klein (Großgmain, Austria) (represented by: H.-J. Ahlt, lawyer)

Defendant: European Commission (represented by: M. Noll-Ehlers, A. Spina and E. Sanfrutos Cano, acting as Agents)

Intervener in support of the defendant: Federal Republic of Germany (represented by: P.-L. Krüger and J. Möller, acting as Agents)

Re:

By his action under Article 263 TFEU, the applicant seeks the annulment of Commission Implementing Decision C(2023) 2961 final of 28 April 2023 on a measure prohibiting the placing on the market of the medical device Inhaler Broncho-Air®, manufactured by Primed Halberstadt Medizintechnik GmbH on behalf of Broncho-Air Medizintechnik AG.

Operative part of the judgment

The Court:

1. Annuls Commission Implementing Decision C(2023) 2961 final of 28 April 2023 on a measure prohibiting the placing on the market of the medical device Inhaler Broncho-Air®, manufactured by Primed Halberstadt Medizintechnik GmbH on behalf of Broncho-Air Medizintechnik AG;
2. Orders the European Commission to bear its own costs and to pay those incurred by Mr Christoph Klein;
3. Orders the Federal Republic of Germany to bear its own costs.

⁽¹⁾ OJ C 321, 11.9.2023.