



## Reports of Cases

### Joined Cases C-495/21 and C-496/21

**L. GmbH  
and  
H. Ltd**

**v**

**Bundesrepublik Deutschland**

(Requests for a preliminary ruling from the Bundesverwaltungsgericht)

### Judgment of the Court (Seventh Chamber) of 19 January 2023

(Reference for a preliminary ruling – Medical devices – Directive 93/42/EEC – Article 1(2)(a) – Definition – Article 1(5)(c) – Scope – Medicinal products for human use – Directive 2001/83/EC – Article 1(2) – Definition of the concept of ‘medicinal product’ – Article 2(2) – Applicable legal framework – Classification as a ‘medical device’ or as a ‘medicinal product’)

1. *Approximation of laws – Medicinal products for human use – Directive 2001/83 – Scope – Definition of medicinal product – Medicinal products by presentation – Medicinal products by function – Included*  
(European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Arts 1(2)(a) and (b) and 2(2))

(see paragraphs 27-29, 35, operative part 1)

2. *Approximation of laws – Medicinal products for human use – Directives 93/42 and 2001/83 – Distinction between medicinal products and medical devices*  
(European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Art. 1(2)(a) and (b); Council Directive 93/42, as amended by Directive 2007/47, Art. 1(2)(a))

(see paragraph 34)

3. *Approximation of laws – Medical devices – Directive 93/42 – Scope*  
(Council Directive 93/42, as amended by Directive 2007/47, Arts 1(2)(a) and (5)(c), 3 and 4)

(see paragraphs 37-41, 49, operative part 2)

4. *Approximation of laws – Medicinal products for human use – Directive 2001/83 – Classification of a product as a medicinal product by function – Criteria – Product with a principal mode of action that is not scientifically established – Not included*  
(European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Art. 1(2)(b))

(see paragraphs 42-44, 49, operative part 2)

5. *Approximation of laws – Medicinal products for human use – Directive 2001/83 – Classification of a product as a medicinal product by presentation – Criteria*  
(European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Art. 1(2)(a))

(see paragraphs 45-49, operative part 2)

See the text of the decision.