



Reports of Cases

Case C-219/11

**Brain Products GmbH
v
BioSemi VOF and Others**

(Reference for a preliminary ruling from the Bundesgerichtshof)

(Reference for a preliminary ruling — Medical devices — Directive 93/42/EEC — Scope — Interpretation of the concept of ‘medical device’ — Product marketed for non-medical use — Investigation of a physiological process — Free movement of goods)

Summary — Judgment of the Court (Third Chamber), 22 November 2012

1. *EU law — Interpretation — Methods — Literal, systematic and teleological interpretation*
2. *Approximation of laws — Medical devices — Directive 93/42 — Scope — Produit marketed for a non-medical use — Not included*

(Council Directive 93/42, as amended by European Parliament and Council Directive 2007/47, Art. 1(2)(a), third indent)

1. See the text of the decision.

(see para. 13)

2. The third indent of Article 1(2)(a) of Directive 93/42 concerning medical devices must be interpreted as meaning that the concept of ‘medical device’ covers an object conceived by its manufacturer to be used for human beings for the purposes of investigating a physiological process only if it is intended for a medical purpose.

In so far as Directive 93/42 must reconcile the free movement of medical devices with the protection of patient’s health, it cannot have the effect of limiting the free movement of medical devices by providing for an obligation of certification and CE marking in respect of those products only where such a limitation is necessary for the protection of public health. It follows that the certification of a product as a medical device cannot be required for a product which is not concerned by its manufacturer to be used for medical purposes even if it is used in a medical context.

(see paras 17, 28-30, 33, operative part)