European Union

“Boston Scientific”

**Decision of the European Court of Justice (Ninth Chamber)
25 October 2018 – Case No. C–527/17**

Boston Scientific Ltd

**Regulation (EC) No 469/2009; Directive 93/42/EEC,
Art. 1(4)**

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Keywords Supplementary protection certificate · Medicinal product for human use · Administrative authorisation procedure · Marketing authorisation procedure · Incorporation as an integral part of a medicinal product · Medical device

1. Article 2 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that a prior authorisation procedure, under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, for a device incorporating as an integral part a substance, within the meaning of Article 1(4) of that directive as amended, cannot be treated in the same way, for the purposes of applying that regulation, as a marketing authorisation procedure for that substance under Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, even if that substance was the subject of the assessment provided for in the first and second paragraphs of section 7.4 of Annex I to Directive 93/42, as amended by Directive 2007/47.

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