

**Judgment of the Court (First Chamber) of 6 May 2021 (request for a preliminary ruling from the Consiglio di Giustizia amministrativa per la Regione Siciliana — Italy) — *Analisi G. Caracciolo srl v Regione Siciliana — Assessorato regionale della salute — Dipartimento regionale per la pianificazione, Regione Sicilia — Assessorato della salute — Dipartimento per le attività sanitarie e osservatorio, Accredia — Ente Italiano di Accreditamento, Azienda sanitaria provinciale di Palermo***

**(Case C-142/20) <sup>(1)</sup>**

***(Reference for a preliminary ruling — Approximation of laws — Regulation (EC) No 765/2008 — Requirements for accreditation and market surveillance relating to the marketing of products — Single national accreditation body — Issuing of the accreditation certificate to conformity assessment bodies — Accreditation body having its seat in a third State — Article 56 TFEU — Article 102 TFEU — Articles 20 and 21 of the Charter of Fundamental Rights of the European Union — Validity)***

**(2021/C 278/29)**

*Language of the case: Italian*

### **Referring court**

Consiglio di Giustizia amministrativa per la Regione Siciliana

### **Parties to the main proceedings**

*Applicant:* Analisi G. Caracciolo srl

*Defendants:* Regione Siciliana — Assessorato regionale della salute — Dipartimento regionale per la pianificazione, Regione Sicilia — Assessorato della salute — Dipartimento per le attività sanitarie e osservatorio, Accredia — Ente Italiano di Accreditamento, Azienda sanitaria provinciale di Palermo

*Intervening party:* Perry Johnson Laboratory Accreditation Inc.

### **Operative part of the judgment**

1. Article 4(1) and (5) as well as Article 7(1) of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Council Regulation (EEC) No 339/93 must be interpreted as precluding the interpretation of national legislation according to which accreditation may be performed by bodies other than the single national accreditation body, within the meaning of that regulation, which have their seat in a third State, even where those bodies ensure compliance with international standards and demonstrate, *inter alia* by means of mutual recognition arrangements, that they have a qualification equivalent to that of the said single accreditation body.
2. Consideration of the second question referred for a preliminary ruling has revealed nothing capable of affecting the validity of the provisions of Chapter II of Regulation No 765/2008 in the light of Articles 56 and 102 TFEU as well as Articles 20 and 21 of the Charter of Fundamental Rights of the European Union.

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<sup>(1)</sup> OJ C 209, 22.6.2020.