



EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 201

Communication from the Commission - TRIS/(2024) 2186

Directive (EU) 2015/1535

Notification: 2024/0240/DE

Forwarding of the response of the Member State notifying a draft (Germany) to of European Commission.

MSG: 20242186.EN

1. MSG 201 IND 2024 0240 DE EN 05-09-2024 16-08-2024 DE ANSWER 05-09-2024

2. Germany

3A. Bundesministerium für Wirtschaft und Klimaschutz, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 512

4. 2024/0240/DE - S00S - HEALTH, MEDICAL EQUIPMENT

5.

6. "The Federal Republic of Germany supports the detailed opinions of the European Commission and the Kingdom of Belgium and the comment of the Republic of Poland; the provisions of Section 12 and Section 2(2)(9) of the notified draft 'Health IT-Interoperability Governance Regulation' on 'accreditation' are no longer included. Consequently, the notified draft no longer provides for 'the verification of the technical and organisational capacity of applicants to carry out a conformity assessment procedure [...] through an accreditation procedure [...] and the ongoing monitoring of compliance with the relevant requirements [...]'.

European Commission

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