

# New European Regulation for better control of marketed products

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The European Parliament and Council approved a new European Regulation [\(EU\) 2019/1020](#) [1] ("Requirements to the CE-Mark, Criteria for appointing and operation of Notified Bodies and Market Authorities") on 20 June 2019. This amends the Directive [2004/42/EC](#) [2] plus the Regulations [\(EC\) 765/2008](#) [3] and [\(EU\) 305/2011](#) [4] concerning control of products entering the European market.

It covers all products under the EU sector-specific regulations, such as the Low Voltage Directive and the Medical Device Directive.

## The reasons given for this new Regulation are:

- Increased number of illegal and dangerous products
- Majority of non-compliant products from outside Europe
- Undue distortion of competition
- Inefficient market surveillance and cross-border coordination
- On-line shopping with products going directly from manufacturer to consumer

## Some of the main changes are:

- Extending/specifying the role of the European representative:
- Must be established within EU/[EEA](#) [4], have responsibility for the compliance documentation, and be identified with contact details, on or with the product
- Same rules apply for online shopping
- Extending/specifying the role of customs at borders:
- Stop products that are not marked or labelled correctly, including CE-marking and identification of European representative
- Establish network for coordination between the market surveillance authorities in the member states

The new Regulation shall be in force from 16 July 2021.

For more information, please contact [Jonlvar.Tidemann@nemko.com](mailto:Jonlvar.Tidemann@nemko.com) [5]

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## Links

[1] [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2019.169.01.0001.01.ENG&toc=OJ.L.:2019:169:TOC&utm\\_campaign=unspecified&utm\\_content=unspecified&utm\\_medium=email&utm\\_source=apsis-anp-3](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.169.01.0001.01.ENG&toc=OJ.L.:2019:169:TOC&utm_campaign=unspecified&utm_content=unspecified&utm_medium=email&utm_source=apsis-anp-3)

[2] [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004L0042&utm\\_campaign=unspecified&utm\\_content=unspecified&utm\\_medium=email&utm\\_source=apsis-anp-3](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004L0042&utm_campaign=unspecified&utm_content=unspecified&utm_medium=email&utm_source=apsis-anp-3)

[3] [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0765&utm\\_campaign=unspecified&utm\\_content=unspecified&utm\\_medium=email&utm\\_source=apsis-anp-3](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0765&utm_campaign=unspecified&utm_content=unspecified&utm_medium=email&utm_source=apsis-anp-3)

[4] [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32011R0305&utm\\_campaign=unspecified&utm\\_content=unspecified&utm\\_medium=email&utm\\_source=apsis-anp-3](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32011R0305&utm_campaign=unspecified&utm_content=unspecified&utm_medium=email&utm_source=apsis-anp-3)

[5] <mailto:Jonlvar.Tidemann@nemko.com>