SOŁTYSIŃSKI KAWECKI SZLĘZAK

Obligations of medical device distributors – new CJEU judgment

On 4 June 2026, the Court of Justice of the European Union ("***CJEU***") issued an important judgment concerning the interpretation of the obligations of medical device distributors under Regulation 2017/745[1] on medical devices ("***MDR***"). The judgment addresses several key questions regarding **the liability of distributors for the conformity of a medical device**.

Facts

Cattani Deutschland is a German distributor of 'non-lubricated' dry air compressors for the production of compressed air used in dentistry. A competitor of the company reviewed the regulatory compliance of devices and found that, although they bore the CE marking, the manufacturer's EU declaration of conformity referred solely to the Machinery Directive 2006/42, omitting any reference to medical device regulations. Moreover, the devices did not bear the four-digit identification number of a notified body, as required for risk class IIa. Consequently, the competitor issued a cease and desist notice to Cattani. Cattani refused to comply – the manufacturer confirmed that the device was not a medical device, and BfArM concluded that supervisory measures were not necessary and that the device could remain on the market. **The case was ultimately referred to the CJEU, which was asked to interpret the scope of distributors' obligations under Article 14(1) and Article 14(2), first subparagraph, point (a), and third subparagraph of the MDR.**

CJEU Judgment (C-10/24)

In its judgment, the CJEU interpreted the due diligence obligations of distributors and held as follows:

1. a distributor is required to verify, on the basis of the information available to it, whether the CE marking and the EU declaration of conformity of the device it makes available on the market manifestly relate to a device covered by the MDR;

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

July 2026

2. a distributor is not required to verify whether the device it makes available should be classified in a specific risk class;
3. however, if the information available to the distributor indicates that the device it makes available has been classified by the manufacturer in a risk class requiring the involvement of a notified body, then, as part of its due diligence, the distributor should verify whether the identification number of that notified body has been indicated;
4. Article 14(2), third subparagraph of the MDR is to be interpreted as meaning that a cease and desist notice issued by a competitor may constitute a basis for a distributor to consider that a device is non-compliant with the Regulation. However, a distributor does not breach its obligations by acting in accordance with the manufacturer's opinion contesting the alleged non-compliance – unless that opinion is manifestly unfounded. A clear and reasoned opinion of the competent national authority denying the non-compliance dispels any doubts as to the conformity of the device.

Although the obligations set out in the MDR have been applicable since 2021, some of them may still give rise to interpretive difficulties. If you make medical devices available on the market as part of your business activities – please do not hesitate to contact us!

Contact us!

Jacek Myszko
Partner, attorney-at-law
✆ +48 660 617 009
✉ jacek.myszko@skslegal.pl

Katarzyna Wójcik-Welc
Associate, attorney-at-law
✆ +48 539 673 159
✉ katarzyna.wojcik-welc@skslegal.pl

Zuzanna Osiej
Associate
✆ +48 538 156 787
✉ zuzanna.osiej@skslegal.pl

This material has been prepared to inform SK&S' clients of certain significant changes in Polish law and does not constitute legal advice regarding the specific circumstances of any client and should not be treated by clients as such. If you have any questions regarding the legal issues outlined above and their potential impact on your business operations in Poland, please contact the lawyer handling your case.