SOŁTYSIŃSKI KAWECKI SZLĘZAK

Legal Alert

August 2025 | www.skslegal.pl

Medical devices available on online platforms – new guidelines from the Medical Devices Coordination Group ("MDCG")

Devices that are software cover a wide range of applications, including applications designed to control insulin pumps, and applications for detecting and diagnosing skin cancers (e.g. melanoma).

Medical devices that are applications can be made available through manufacturers' websites and also through the marketplace.

What regulations apply?

As a general rule, if more than one piece of EU legislation may apply to a product, it can only be made available on the market **if the product complies with all applicable EU harmonisation regulations**. If an application that is a medical device is sold through a platform, not only do the EU medical device regulations[1,2] apply, but also the DSA[3].

Several acts – many roles?

Will an online platform provider always be considered an importer or distributor? This is a question many entities have been asking themselves. The MDCG, which issued specific guidelines in June 2025, has provided the answers.

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices ("**MDR**")
[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices ("**IVDR**")
[3] Regulation (Eu) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services ("**DSA**")

i. Platform provider = distributor/importer of medical device

The MDCG describes examples of situations in which a platform provider is considered a distributor/importer of a medical device that is software:

1) the manufacturer makes the medical device, which is the application, available to the provider of the app platform, who then makes it available directly to the user as a distributor. This could involve transferring ownership or other rights

or

2) if the manufacturer of the medical device application is based outside the European Union and the app platform provider is based in the EU, he will act as an importer of the medical device. Obligations relating to the device, such as the establishment of an authorised representative, remain with the manufacturer.

In this case, the regulations for medical device distributors/importers described in the MDR and IVDR apply.

ii. Platform supplier ≠ distributor/importer of the medical device

If the platform provider **only enables the medical device manufacturer to conclude distance contracts with the buyer** (by hosting the application on its platform) - it does not act as a distributor/importer of the medical device.

In this case, the obligations under the DSA will apply, not the MDR or IVDR.

When is an application that is a medical device marketed, and when is it made available? What information obligations do medical device operators have, and what should online platform providers verify? If you need answers to these and other questions about medical devices, 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

Warszawa
Jasna 26, 00-054 Warszawa
T +48 22 608 70 00
F +48 22 608 70 70
E office@skslegal.pl

Katowice
Korfantego 138a, 40-156 Katowice
T +48 32 731 59 86
F +48 32 731 59 90
E office.katowice@skslegal.pl

Poznań
Mickiewicza 35, 60-837 Poznań
T +48 61 856 04 20
F +48 61 856 05 67
E office.poznan@skslegal.pl

www.skslegal.pl