KYRIAKIDES GEORGOPOULOS
LAW FIRM

LIFE SCIENCES & HEALTHCARE PRACTICE

Responsibilities of Authorized Representatives in light of MDCG 2022-16 Guidance

December 2022

Responsibilities of Authorized Representatives in light of MDCG 2022-16 Guidance

BY AITHRA ANTONIADOU

The guidance document issued by MDCG is addressed to authorized representatives, manufacturers and other economic operators, providing advice and clarifications on relevant requirements under Regulation (EU) 2017/745, i.e. Medical Devices Regulation ("MDR"), and Regulation (EU) 2017/746, i.e. In Vitro Diagnostic Regulation ("IVDR"). The most noteworthy terms of the guidance are summarized as follows:

Designation and mandate

The designation constituting the authorized representative's mandate shall (i) be valid only if accepted in writing by the authorized representative and (ii) be effective at least for all devices of the same generic device group.

The manufacturer and the authorized representative are free to configure the structure of their contractual relationship upon the condition that a written mandate complies with the requirements of Article 11(3) of MDR/IVDR.

Paragraphs (3) and (4) of articles 11 of MDR/IVDR provides for the minimum tasks that the mandate should contain, which the manufacturer should enable the authorized representative to perform. However, the manufacturer is not permitted to delegate the obligations of Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11),(12) of MDR and Article 10(1), (2), (3), (4), (5), (6), (8), (9), (10) and (11) of IVDR respectively.

The mandate should enable the authorized representative to terminate it, if the manufacturer acts contrary to its obligations. It should be noted that the termination of the mandate is only possible with respect to the whole generic device group and not a specific device within that group, unless the specific device is removed/withdrawn from the market and, hence, is outside the scope of the effective mandate.

Registration & verification obligations

Authorized representatives must register in EUDAMED providing the information specified in Section 1 of Part A of Annex VI of MDR/IVDR.

Minimum tasks & responsibilities

Pursuant to the provisions of MDR and IVDR, the authorized representatives shall:

(a) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements of such documents, at the disposal of competent authorities for at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market, or in the case of implantable devices, for at least 15 years after the last device has been placed on the market.

(c) comply with the registration obligations of Article 31 and verify that the manufacturer has complied with the registration obligations of Articles 27 and 29;

(d) provide to any competent authority, upon request, all the information and documentation in order to demonstrate the conformity of devices;

(e) forward to the manufacturer any request for samples or access to a device by any competent authority of the Member State where the authorized representative has its registered seat and ensure that the competent authority receives those samples or is given access to the device as requested;

(f) cooperate with the competent authorities as regards any preventive or corrective action and to eliminate or mitigate the risks;

(g) immediately inform the manufacturer about any complaints and reports as regards devices;

(h) terminate the mandate in case the manufacturer acts contrary to its obligations.

Liability

Liability, according to Article 11(5) of MDR/IVDR, should be interpreted so as (i) the manufacturer cannot delegate its obligations under Article 11(4) and (ii) the authorized representative may remain liable for defective devices, if the manufacturer has not complied with the obligations under Article 10 of MDR/IVDR.

The authorized representative's potential joint liability is conditional, upon the manufacturer's failure to comply with its obligations. Therefore, the authorized representative could be liable in case of (a) manufacturer's liability as regards a defective device under applicable legislation and (b) manufacturer's failure to comply with its obligations under Article 10 of MDR/IVDR.

For further information: MDCG 2022-16 - Guidance on Authorised Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746 - October 2022 (europa.eu)

Contact Us

Irene Kyriakides
PARTNER
i.kyriakides@kglawfirm.gr

Victoria Mertikopoulou
PARTNER
v.mertikopoulou@kglawfirm.gr

Follow Us

ATHENS OFFICE

28, Dimitriou Soutsou Str.,
115 21 Athens

T +30 210 817 1500
F +30 210 685 6657-8
E kg.law@kglawfirm.gr

THESSALONIKI OFFICE

31, Politechniou Str.,
551 34 Thessaloniki

T +30 2310 441 552
E kg.law@kglawfirm.gr

www.kglawfirm.gr