
DRAFT STATUTORY INSTRUMENTS

2021 No.

The Medical Devices (Northern
Ireland Protocol) Regulations 2021

PART 6

Enforcement

Offence of breaching certain provisions

23.—(1) A person commits an offence if the person contravenes a prohibition or fails to comply with a requirement in a provision of the regulations listed in Table 1 or the Articles listed in Table 2 in Schedule 3 to these Regulations.

(2) A person guilty of an offence under paragraph (1) is liable on summary conviction to imprisonment for a term not exceeding 6 months, to a fine not exceeding level 5 on the standard scale or to both.

(3) In respect of an offence under this regulation, a magistrates' court in Northern Ireland may hear and determine any complaint made before the earlier of—

- (a) the end of the period of 1 year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and
- (b) the end of the period of 3 years beginning with the day on which the offence was committed.

(4) For the purposes of paragraph (3)(a)—

- (a) a certificate signed by or on behalf of the prosecutor and stating the date on which such evidence came to the prosecutor's knowledge is conclusive evidence of that fact, and
- (b) a certificate stating that matter and purporting to be so signed is to be treated as so signed until the contrary is proved.

Defence of due diligence

24.—(1) It is a defence for a person charged with an offence under regulation 23(1) to show that the person took all reasonable steps and exercised all due diligence to avoid commission of the offence.

(2) If in any proceedings for such an offence the defence provided by paragraph (1) involves an allegation that the commission of the offence was due to—

- (a) an act or default of another person, or
- (b) reliance on information given by another person,

the defendant is not, without leave of the court, entitled to rely on that defence unless the requirement in paragraph (3) is satisfied.

(3) The requirement is that at least 7 clear days before the hearing of the proceedings the defendant has served on the prosecutor a notice giving such information identifying or assisting in the identification of that other person as was then in the defendant's possession.

(4) A defendant is not entitled to rely on the defence provided by paragraph (1) by reason of the defendant's reliance on information supplied by another person unless the defendant shows that it was reasonable in all the circumstances to rely on the information, having regard in particular to—

- (a) the steps which the defendant took or might reasonably have taken to verify the information, and
- (b) whether the defendant had any reason to disbelieve the information.

Offences by bodies corporate

25.—(1) Where an offence under regulation 23(1) committed by a body corporate or a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, an officer, the officer (as well as the body corporate or partnership) commits the offence and is liable to be proceeded against and punished accordingly.

(2) In relation to a body corporate, "officer" means—

- (a) a director, manager, secretary or other similar officer of the body, or
- (b) a person purporting to act in any such capacity.

(3) In paragraph (2)(a), "director", in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

(4) In relation to a Scottish partnership, "officer" means—

- (a) a partner, or
- (b) a person purporting to act as a partner.

Enforcement

26.—(1) It is the duty of the Secretary of State to enforce these Regulations and Regulation (EU) 2017/745.

(2) It is the duty of each district council in Northern Ireland to enforce these Regulations and Regulation (EU) 2017/745 within its area (concurrently with the Secretary of State) in relation to devices that are ordinarily intended for private use or consumption.