STATUTORY INSTRUMENTS

# 2024 No. 221

# The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024

## PART 4

## Amendments to the Medical Devices (Northern Ireland Protocol) Regulations 2021

**New Part 2A (Making available on the market and putting into service under Regulation (EU) 2017/746)**

**33.** After Part 2 insert—

## "Part 2A

## Making available on the market and putting into service under Regulation (EU) 2017/746

**Certificates of free sale under Regulation (EU) 2017/746 – fee**

**10A.** A manufacturer or authorised representative who requests a certificate of free sale from the Secretary of State under Article 55 must pay to the Secretary of State a fee of £75.

**Retention of documentation relating to conformity assessments**

**10B.**—(1) The liquidator or trustee in bankruptcy of a manufacturer, or of an authorised representative, must—

(a) retain for the required period any documentation that consists of, or reasonably could consist of, information to which section 7 of Annex IX applies, and

(b) comply with any request made by the Secretary of State during the required period to provide the Secretary of State with the retained documentation.

(2) In this regulation, the required period is 10 years after the last device was placed on the market.

**UK(NI) indication under Regulation (EU) 2017/746**

**10C.**—(1) This regulation applies if the CE marking is affixed in accordance with Article 18 on the basis of a certificate issued by a notified body established in the United Kingdom.

(2) The CE marking must be accompanied by the UK(NI) indication.

(3) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies.

(4) The manufacturer must affix the UK(NI) indication—

(a) visibly, legibly and indelibly, and

(b) before placing the device on the market.

(5) A person may only make available on the market a device to which this regulation applies if the manufacturer has affixed the UK(NI) indication in accordance with this regulation.”.