DRAFT STATUTORY INSTRUMENTS

2021 No.

The Medical Devices (Northern Ireland Protocol) Regulations 2021

PART 2

Making available on the market and putting into service under Regulation (EU) 2017/745

UK(NI) indication

10.—(1) This regulation applies if the CE marking is affixed in accordance with Article 20 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 or putting the device into service.

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

(6) In this regulation, "the UK(NI) indication" means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020(**1**).

(**1**) S.I. 2020/1460.