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STATUTORY INSTRUMENTS

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**2021 No. 905**

The Medical Devices (Northern  
Ireland Protocol) Regulations 2021

PART 8

Amendment of the Medical Devices Regulations 2002

**Amendment of regulation 36A (UK(NI) indication: in vitro diagnostic medical devices)**

**37.** In regulation 36A, after paragraph (3), insert—

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

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**Commencement Information**

**11** Reg. 37 in force at 27.7.2021, see [reg. 1\(2\)](#)

**Changes to legislation:**

There are currently no known outstanding effects for the The Medical Devices (Northern Ireland Protocol) Regulations 2021, Section 37.