should only take action if you consider that you are potentially able to meet the essential technical requirements set out in Table 1 or 2, below, as relevant to your product.

For products where a manufacturer claims a double/dual purpose – for example the item could be used to protect both the patient and the healthcare worker the MHRA approval letter will cover the medical device regulatory consideration only. You must therefore also meet the relevant basic health and safety requirements (BHSR) of the PPE Directive. In cases of proposed dual-purpose the Regulators (HSE and MHRA) will work in partnership to ensure that the relevant authorisation/derogation is in place to enable this where the required essential technical standards are met.