Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

07 February 2024

FOI 24/040

Dear [redacted]

Thank you for your information request, dated 12 January 2024

Your Request

Which of the four guidelines listed were adhered to for Nitrile Gloves-

1. EU PPE Regulation 2016/425 – dated 09th March 2016New High-Volume Manufacturers of COVID-19 Personal Protective Equipment (PPE) and Medical Device PPE - dated 05th May 2020
2. The Personal Protective Equipment(Enforcement) Regulations 2018 – dated 21st April 2018
3. The Medical Devices Regulations 2002

We were aware that DHSC had followed the HM Government's guidelines (the new high- volume manufacturers of COVID-19 personal protective equipment and medical device PPE as of May 5th, 2020) which stated -'This guidance is for you if you want to make and supply high volumes of gowns, gloves, masks, respirators, eye protection, aprons and coveralls to the UK to protect health and care workers from Covid-19 and the item does not have a CE mark or you wish to propose the alternative use of an existing CE marked product against the relevant legislation'

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We would be grateful if you could tell us if UK government followed New High-Volume Manufacturers of COVID-19 Personal Protective Equipment (PPE) and Medical Device PPE - dated 05th May 2020 for conducting Technical Reassurance of Nitrile Gloves between 5th May 2020 and 5th November 2020.

Your response

I can confirm that I have received your email.

However, I regret that it does not constitute a valid request as you have not provided your name as per guidance below.

S8(1) of the Freedom of Information Act states that a valid request:

(a) is in writing,

(b) states the name of the applicant and an address for correspondence, and

(c) describes the information requested.

Freedom of Information Act 2000 (legislation.gov.uk)

The regulator of the Act (the Information Commissioner) has provided guidance on what this means:
[1]http://ico.org.uk/for_organisations/guid...

On the subject of 'name', this guidance states: "In our view, the intention of the legislation is for the requester to provide their real name so their request could be processed in accordance with the requirements of the FOIA". An example that they give is:

A requester named Robert Jones could call themselves ‘Rob Jones’, ‘Bobby Jones’, ‘R Jones’, ‘Bob Jones’ or ‘Mr Jones’. However, they could not just use ‘Robert’, ‘Bob’, ‘Bobby’ or ‘R.J’."

Under advice and assistance under the FOI legislation, we can provide you with some links in relation to PPE and Regulatory status of equipment. Please be aware that this request sit more firmly with UKSHA and HSE and would advise you to put a narrowed request to these agencies:

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UK Health Security Agency - GOV.UK (www.gov.uk)

HSE: Information about health and safety at work

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If you have a query about the information provided, please reply to this email

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

FOI Team

MHRA Customer Service