Date: 09/04/2021

[redacted]

To [redacted]
cc [redacted]
bcc

SubjectFW: REMINDER: MHRA Ref: [redacted]

[redacted]
Higher Medical Device Specialist
Devices – Safety & Surveillance

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU, UK
Email: [redacted]
Direct line: [redacted]

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Medicines & Healthcare products Regulatory Agency

Ensure your Medical Devices are registered with the MHRA.
Find out more at: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market

Read our guidance on coronavirus (COVID-19)

From: [redacted]
Sent: 09 April 2021 11:16
To: [redacted]
Cc: [redacted]
Subject: RE: REMINDER: MHRA Ref: [redacted]

Dear [redacted]

Please find attached information as requested.

[redacted]

Kind Regards

[redacted]

Tel: [redacted]
Email : [redacted]

B. Braun Medical Ltd, Brookdale Road, Sheffield, S35 2PW.

We believe in improving people's health through everything we do.
Through constructive dialogue, B. Braun develops high quality product systems and services that are both evolving and progressive. B. Braun is one of the world's leading manufacturers of medical devices, pharmaceutical products and services.

B. Braun - Sharing Expertise

From: [redacted] [mailto: [redacted]
Sent: 08 April 2021 17:19
To: [redacted]
Cc: [redacted]
Subject: REMINDER: MHRA Ref: [redacted]

Dear [redacted]

Please can you respond to the formal MHRA questions from the e-mail dated: 18/03/21 (below), a response was required by Tuesday 7th April 21.

I would appreciate it if you could complete this by **2pm Monday 12 th April 2021.**

Thank you.

Kind regards,

[redacted]
Higher Medical Device Specialist

Devices – Safety & Surveillance

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU, UK

Email: [redacted]

Direct line: [redacted]

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Read our guidance on coronavirus (COVID-19)

Date: 18/03/2021 **To:** [redacted]

From: [redacted]

bcc

Subject: FSN/FSCA Initial Letter MHRA Ref: [redacted]

Attachments: <<>>

Dear [redacted]

18/03/2021

MHRA Ref: [redacted] **quote this in any reply**

Your Ref [redacted] **,** [redacted] **&** [redacted]

Thank you for submitting your Field Safety Notice (FSN), which we will publish on the government's website.

What you need to do now

- Use the Medical Device Safety Officer (MDSO) contact list on MORE to help you target the FSN within the MDSO's organisation.
- Use the effective FSN guidance for advice on writing clear notices and maximising replies to your FSN's.

What you need to do within 20 working days of the date of this email

- Provide **all** the extra information detailed in the annex, if you haven't already done so. Add this to box 7 of the FSCA form or the 'Description of the FSCA' tab on MORE and re-submit it as a follow-up report.

If you can't answer all the questions now, answer as many as you can and tell us when you expect to send the rest of the information.

What you need to do after 20 working days

- If the FSCA is not complete, provide regular updates on points 2.6 and 2.7 of the annex.

Yours sincerely
Adverse Incidents & Communications Team
MHRA, Devices

Note
Use this email address aic@mhra.gov.uk to contact us. We check it regularly.

Annex: Extra information we need in section 7 of your FSCA report

1. **Risk assessment for the FSCA including:**

1.1. How many incidents have you received related to this FSCA?

1.2. What is the hazard presented by using the device with this issue? Send us a copy of the Health Hazard Evaluation (HHE) or Clinical risk assessment report.

1.3. If this is a batch issue, why it is restricted to these batches only?

1.4. Do you know if this issue affects other CE-marked devices? (eg own-brand labelled products).

1.5. Provide update on root cause investigation / conclusions of tests and other investigations on suspect or other samples.

1.6. Provide details of long-term corrective actions.

2. **Where the FSCA applies to the UK**:

2.1. What is the FSN distribution list (named contacts and locations)? Include any additional people who will be sent the letter (chief executives, Medical Device Safety Officers (MDSOs), medical directors, community pharmacists etc). You can send us this as a separate document.

2.2. How will you contact the end user if affected customers include distributors? Send us a copy of the list of distributors. Confirm who will be managing the FSCA and compiling reconciliation data for these end users.

2.3. How many sites are affected in the UK? How many devices/tests did each site receive?
You can send us this as a separate document.

2.4. When was the affected product distributed/installed?

2.5. How will you monitor the extent to which the FSN message has been received? (eg fax-back form / telephone follow-up). What are your key dates for actions?

2.6. How many UK sites have confirmed receipt of your FSN?

2.7. How many UK sites have confirmed that they have successfully undertaken the action(s) specified in your FSN?

2.8. What is the expected date of completion of the field safety corrective action?

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in error, please notify us immediately by return e-mail and destroy this communication and all copies thereof, including all attachments.