Date: 23/11/2021
From: [redacted]/MHRA

To [redacted]
cc [redacted], [redacted]@bbraun.com
bcc

Subject [redacted]ormation request MHRA Ref: [redacted]

Dear B. Braun,

Regarding the FSN/FSCA we have still not received a response to outstanding request for further information.

Please could you provide an update of the number of total acknowledgements to date.

I have also received an email from Great Ormond Street Hospital regarding this FSN enquiring as to why they did not didn,t receive the alert from the manufacturer and patients were treated with faulty batches after the alert was issued. Please can you clarify as to why this hospital was not included in your customer list and did not receive the FSN?

Please be reminded that it is a requirement for the manufacturer to inform all customers of the FSN and coordinate with the competent authority where further clarification or information is required.

I look forward to your response by **Friday 26th November.**

Kind regards

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

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

gov.uk/mhra
Stay connected

Date: 12/11/2021
From: [redacted]/MHRA

To [redacted]
cc [redacted]
bcc

SubjectRe: MHRA Ref: [redacted]

Dear [redacted],

Regarding the FSN/FSCA we have still not received a response to outstanding request for further information.

Please could you provide an update of the number of total acknowledgements to date.

I have also received an email from Great Ormond Street Hospital regarding this FSN enquiring as to why they did not didn,t receive the alert from the manufacturer and patients were treated with faulty batches after the alert was issued. Please can you clarify as to why this hospital was not included in your customer list and did not receive the FSN?

I look forward to your response by **Friday 19th November.**

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

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

gov.uk/mhra
Stay connected

Register your medical devices with MHRA

Read our guidance on coronavirus (COVID-19)

MHRA launched a public consultation on future UK medical device regulations on 16 September 2021, which will close on 25 November 2021. Find out more here. The consultation documents can be found here.

Date: 03/11/2021
From: [redacted]/MHRA

To [redacted]
cc
bcc

Subject MHRA Ref: [redacted]

Dear [redacted],

Regarding the FSN/FSCA we have still not received a response to the most recent email.

Please can you provide the requested further information and update outlined in the email below by **Friday 5th November.**

Kind regards

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

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU
Direct line: [redacted]

gov.uk/mhra
Stay connected

Register your medical devices with MHRA

Read our guidance on coronavirus (COVID-19)

MHRA launched a public consultation on future UK medical device regulations on 16 September 2021, which will close on 25 November 2021. Find out more here. The consultation documents can be found here.

Date: 12/10/2021
From: [redacted]/MHRA

To [redacted]
cc [redacted]
bcc

Subject [redacted] SCA First Reminder MHRA Ref:

Dear [redacted],

Thank you for the previous update.

Please could you provide an update of the number of total acknowledgements to date.

I have also received an email from Great Ormond Street Hospital regarding this FSN enquiring as to why they did not didn,t receive the alert from the manufacturer and patients were treated with faulty batches after the alert was issued. Please can you clarify as to why this hospital was not included in your customer list and did not receive the FSN?

I look forward yo your response by **Tuesday 19th October.**

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

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

gov.uk/mhra
Stay connected

Register your medical devices with MHRA

Read our guidance on coronavirus (COVID-19)

MHRA launched a public consultation on future UK medical device regulations on 16 September 2021, which will close on 25 November 2021. Find out more here. The consultation documents can be found here.

Date: 02/07/2021
From: [redacted]

To [redacted]
cc [redacted]
bcc

Subject [redacted] First Reminder MHRA Ref:

Attachments: *<<see below >>*

-----Original Message-----
From: [redacted]
Sent: 02 July 2021 13:13
To: [redacted]; AIC <AIC@mhra.gov.uk>
Cc: [redacted]
Subject: UPDATE : FSN/FSCA First Reminder MHRA Ref: [redacted]

Good Afternoon [redacted],

I am just providing you with an update in regards to the Histoacryl Recall.

The Reconciliation attached is for the first 2 updates to this recall. We are currently awaiting acknowledgements from 7 customers on this.

The Reconciliation 22.04.2021 attached is for the third update to the recall. On this one we are currently awaiting 48 acknowledgements.

For both of these all customers have been chased today and have been given a deadline of the 16th July 2021 to respond to us. This is the fourth chase that has been completed for the recall.

We will provide you another update following the deadline of this chase.

Kind Regards

[redacted]
Regulatory Affairs & Quality Department

Tel: [redacted]
Email: [redacted]

Please note my normal working days are Thursday & Friday

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

-----Original Message-----
From: [redacted]
Sent: 04 May 2021 15:34
To: [redacted]
Cc: aic@mhra.gov.uk
Subject: FW: FSN/FSCA First Reminder MHRA Ref: [redacted]

Dear [redacted],

Please see attached the updated risk assessment. An update for the corrective action is as follows:

Corrective Actions / Activities Update:
Currently, the investigation is focused in determining the fine tunning adjustment of the S02 concentration in the raw material, a task made in collaboration with the supplier that is performing their own investigation. On the other hand, the optimal transport and storage conditions are being evaluated in order to assess the influence in the S02 equilibrium to avoid the modification of the usual polymerization profile.

Attached is a copy of the acknowledgements we have received to date.

We have provided a further update with additional batches at the end of April. We have therefore also attached for your information the list of acknowledgements that we have received to date from this additional update on the 22.04.2021.

Kind Regards

[redacted]
Regulatory Affairs & Quality Department

Tel: [redacted]
Email: [redacted]

Please note my normal working days are Thursday & Friday

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

-----Original Message-----
From: [redacted]
Sent: 22 April 2021 09:41
To: [redacted]
Subject: FSN/FSCA First Reminder MHRA Ref: [redacted]

22/04/2021

MHRA ref: [redacted] quote this in any reply

Your ref: [redacted]

To date we have not received your final report.

Why we,re writing to you now

We need an update on acknowledgements and progress on any corrective action.

If you haven,t already done so, please provide the information requested in our last

email.

What you need to do now

Send us the information within 10 days of this email so we can decide whether to take further action.

You don,t need to re-send copies of correspondence you have sent us previously.

Yours sincerely
Adverse Incidents & Communications Team
MHRA, Devices

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

You can access the Medical Device Safety Officer (MDSO) contact list via the Manufacturer Online Reporting Environment (MORE) in order to copy them in on communications regarding Field Safety Notices (FSNs). This can help you ensure appropriate targeting and prompt action of the FSN within the MDSO,s organisation.

[attachment "Reconcilation.xlsx" deleted by [redacted]/MHRA] [attachment "Reconciliation 22.04.2021.xlsx" deleted by [redacted]/MHRA]