

Date: 02/07/2021

To: [REDACTED] AIC
<AIC@mhra.gov.uk>

bcc

Subject: [REDACTED] First Reminder MHRA Ref:

-----O g
From: [REDACTED]
Sent: [REDACTED]
To: [REDACTED] <AIC@mhra.gov.uk>
Cc: [REDACTED]
Subject: [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] Analyst
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.

-----O ge-----
From: [REDACTED]
Sent: [REDACTED]
To: [REDACTED]
Cc: [REDACTED]
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 tuning 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]
Analyst
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.

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B. Braun - Sharing Expertise

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From: [REDACTED] [mailto:[REDACTED]]
Sent: [REDACTED]
To: [REDACTED] <[REDACTED]>
Subject: [REDACTED] rs [REDACTED]

22/04/2021

MHRA ref: [REDACTED] quote this in any reply

Your ref: [REDACTED], [REDACTED] & [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.

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