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

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

No reported incidents have been received regarding this issue in the last 5 years.

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?

Please find a copy of the risk assessment attached

1.3. if this is a batch issue, why it is restricted to these batches only?
The recall has been restricted for those Histoacryl batch numbers of which we have the evidence that they are affected.

1.4. do you know if this issue affects other CE-marked devices? (eg own-brand labelled products)
This issue does not affect other CE-marked devices not included in this FSCA.

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

See in the risk assessment attached

1.6. Please provide details of long term corrective actions
A CAPA has been opened to determine corrective actions. The complete investigation is still on-going, therefore the corrective actions are not available yet

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 .

See attached 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.

Please see above. All customers have been contacted by email and with a letter posted.

[redacted] will be managing the FSCA and compiling reconciliation data

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.

28 affected sites – see attached document

2.4. When was the affected product distributed/installed?

Between 14.09.2020 and 17.02.21

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?

All customers were given a deadline of the 3rd April 2021 to return the completed acknowledgement.

A follow up of outstanding customers will be carried out w/c 5th April 2021.

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

11 acknowledgements have been received so far.

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

See 2.6

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

On going.