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Telephone: Direct Dial: [REDACTED]

Reception: [REDACTED]

Fax [REDACTED]

[www.hfs.scot.nhs.uk](http://www.hfs.scot.nhs.uk)

**From:** [REDACTED] (NHS GRAMPIAN)

**Sent:** 07 September 2018 08:50

**To:** [REDACTED] (NHS GRAMPIAN); [REDACTED] (NHS NATIONAL SERVICES SCOTLAND)

**Cc:** [REDACTED] (NHS NATIONAL SERVICES SCOTLAND); [REDACTED] (NHS GRAMPIAN);

[REDACTED] (NHS GRAMPIAN); [REDACTED] (NHS GRAMPIAN); [REDACTED]

**Subject:** RE: INV1145 OCC1365 User Update Letter MHRA Ref: 2018/008/008/291/023

Good Morning [REDACTED]

Would you be able to contact MHRA and suggest a visit on site on the following dates please?

19 -21 November 2018

10 -12 December 2018

Many thanks, [REDACTED]

-----  
[REDACTED]

Central Decontamination Unit  
Foresterhill Health Campus  
Mile End, Aberdeen, AB25 2ZN

TEL: [REDACTED]

MOB: [REDACTED]

EMAIL: [REDACTED]

-----  
**From:** [REDACTED] (NHS GRAMPIAN)

**Sent:** 28 August 2018 17:33

**To:** [REDACTED] (NHS NATIONAL SERVICES SCOTLAND); [REDACTED] (NHS GRAMPIAN);

[REDACTED] (NHS GRAMPIAN)

**Cc:** [REDACTED] (NHS NATIONAL SERVICES SCOTLAND); [REDACTED] (NHS GRAMPIAN);

[REDACTED] (NHS NATIONAL SERVICES SCOTLAND)

**Subject:** RE: INV1145 OCC1365 User Update Letter MHRA Ref: 2018/008/008/291/023

Hi [REDACTED]

Thank you for phoning this afternoon to follow up your email below and apologies for the delay in getting back to you.

It's sound advice you have given around organising a pre-arranged visit with MHRA and on discussion with [REDACTED] this afternoon I believe she is going to take this forward.

Thank you also for offering to facilitate the visit, as this is an offer that we will take you up on.

Also once again thank you for the work that you put into this issue around Wassenburg and Dr Weigert, it was very supportive and hugely appreciated.

Regards

█

█  
█

NHS Grampian  
Central Decontamination Unit  
Foresterhill Health Campus  
Mile End  
Aberdeen  
AB25 2ZN  
TEL: █

**From:** █ (NHS NATIONAL SERVICES SCOTLAND)

**Sent:** 17 August 2018 13:35

**To:** █ (NHS GRAMPIAN); █ (NHS GRAMPIAN); █ (NHS GRAMPIAN)

**Cc:** █ (NHS NATIONAL SERVICES SCOTLAND); █ (NHS GRAMPIAN); █ (NHS NATIONAL SERVICES SCOTLAND)

**Subject:** RE: INV1145 OCC1365 User Update Letter MHRA Ref: 2018/008/008/291/023

Dear █

Please find the attached response from Dr Weigert and MHRA.

In summary, Dr Weigert stated that 'BOTH neodisher Septo PAC and our neodisher endo SEPT PAC are identical in terms of formulation and efficacy performance'.

MHRA stated that you need to carry out risk assessment as a part of your quality system. In addition, I informed MHRA the periodic testing and annual validation of EWDs passed the tests, demonstrating satisfactory outcomes throughout the years. Thus, as per MHRA's email, conducting type testing for a compatible or material identical product may seemed to be excessive.

█ offered to come up to Aberdeen if help still required. As NHS Grampian CDU and EDu are registered with MHRA, and certified to EN 13485. MHRA can advise/accompany the notified body to carry out unannounced audit. Thus you may consider the pre-arranged visit. Please let me know and I can help facilitating his visit.

I hope this helps clarifying the issue. Please don't hesitate to contact us if you require further assistance.

Kind regards,

█  
█

Health Facilities Scotland  
Procurement, Commissioning and Facilities  
NHS National Services Scotland  
3rd Floor Meridian Court  
5 Cadogan Street  
Glasgow

G2 6QE

Telephone: Direct Dial: [REDACTED]

Reception: [REDACTED]

Fax [REDACTED]

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**From:** [REDACTED] (NHS NATIONAL SERVICES SCOTLAND)

**Sent:** 14 August 2018 14:49

**To:** [REDACTED] (NHS GRAMPIAN); [REDACTED] (NHS GRAMPIAN); [REDACTED] (NHS GRAMPIAN)

**Subject:** FW: INV1145 OCC1365 User Update Letter MHRA Ref: 2018/008/008/291/023

Hi [REDACTED], [REDACTED] and [REDACTED],

Please see communication below with MHRA and attached with Dr Weigert.

In my view, this is a regulatory matter.

I will update you once I heard from them.

Kind regards,

[REDACTED]

Health Facilities Scotland  
Procurement, Commissioning and Facilities  
NHS National Services Scotland  
3rd Floor Meridian Court  
5 Cadogan Street  
Glasgow  
G2 6QE

Telephone: Direct Dial: [REDACTED]

Reception: [REDACTED]

Fax [REDACTED]

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**From:** [REDACTED] (NHS NATIONAL SERVICES SCOTLAND)

**Sent:** 14 August 2018 14:44

**To:** [REDACTED]@mhra.gov.uk'

**Cc:** iric (NHS National Services Scotland)

**Subject:** FW: INV1145 OCC1365 User Update Letter MHRA Ref: 2018/008/008/291/023

Dear [REDACTED]

Thanks for your email to IRIC.

The enquiry came from our Deputy First Minister.

We'd be grateful if you can speed up the investigation please.

We have few email exchange with Dr Weigert, please see the attached.

We have all the evidences and copy [REDACTED] on all exchange emails. I suggest that we should continue the investigations rather than starting all over again.

If you require further information, please do not hesitate to contact me directly.

Many thanks

Kind regards,

[REDACTED]

Health Facilities Scotland  
Procurement, Commissioning and Facilities  
NHS National Services Scotland  
3rd Floor Meridian Court  
5 Cadogan Street  
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**From:** [REDACTED] (NHS National Services Scotland)  
**Sent:** 14 August 2018 13:29  
**To:** [REDACTED] (NHS NATIONAL SERVICES SCOTLAND)  
**Cc:** [REDACTED] (NHS NATIONAL SERVICES SCOTLAND); [REDACTED] (NHS NATIONAL SERVICES SCOTLAND); [REDACTED] (NHS NATIONAL SERVICES SCOTLAND); [REDACTED] (NHS NATIONAL SERVICES SCOTLAND)  
**Subject:** FW: INV1145 OCC1365 User Update Letter MHRA Ref: 2018/008/008/291/023

Hi Decon team

Please find below the MHRA User Update Letter received today for your attention on pending case INV1145 OCC1365.

Kind regards

[REDACTED]

[REDACTED]

[REDACTED]

Health Facilities Scotland  
NHS National Services Scotland

**Contact Us:**

Direct Line [REDACTED]  
IRIC Email [REDACTED]@nhs.net  
Helpline [REDACTED]

<http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric-1/>

Please consider the environment before printing this email.

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service. [www.nhsnss.org](http://www.nhsnss.org)



**From:** [REDACTED]@mhra.gov.uk [mailto:[REDACTED]@mhra.gov.uk]  
**Sent:** 14 August 2018 12:30  
**To:** [REDACTED] (NHS National Services Scotland)  
**Subject:** INV1145 OCC1365 User Update Letter MHRA Ref: 2018/008/008/291/023

14/08/2018

**MHRA ref: 2018/008/008/291/023**

**Your ref: OCC1365**

Dear [REDACTED]

Thank you for your report of a medical device adverse incident involving: Device: Disinfectant, Manufacturer: Dr. Weigert UK Ltd

We have assessed your report and have asked the manufacturer to investigate. They may contact you for further information and you can release the device to them.

This investigation may take some time. It can take 3 months or longer to investigate and so you might not hear from us during this time.

When we receive the manufacturer's report we will forward their findings to you.

Every report is important because it adds to our knowledge about medical devices and helps us to develop safety guidance and take appropriate action.

Please keep sending us your reports.

Yours sincerely  
Adverse Incident Centre

**Note**

Use this email address [REDACTED]@mhra.gov.uk to contact us. We check it regularly.

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