From: [redacted]
Sent on: Friday, January 9, 2026 9:15:20 AM
To: [redacted]
CC:

Subject: WG: MHRA Ref: 2025/005/018/501/003_AW: Incident: Prisma SMART max CPAP [ref:_00D0NiROk._500TrdISYy:ref]

Attachments: [redacted]
(117.46 KB), Excerpt from Risk Analysis_Ticket 24466.pdf (176.29 KB), B2506010_Attachment1.pdf (442.59 KB), B2506010_Attachment2.pdf (1.06 MB), B2506010_Attachment3.pdf (1.21 MB)

Dear [redacted]

thank you very much for your additional requests. Please find below our responses:

1. In your latest response to MHRA, you reference your material characterization results and the degradation and aging assessments. Please can you provide these?

The biocompatibility evaluation for WM090TD has been performed in accordance with ISO 10993-1 and ISO 18562-1 and is documented in the Biological Evaluation Plan (BEP) and Biological Evaluation Report (BER).

The evaluation includes material characterization, degradation considerations, and assessments following production and accelerated aging. Specifically:
- The biocompatibility assessment of the constituent materials, including material characterization, is documented in the Biological Evaluation Report, pages 8–18.
- Particulate matter emissions testing of the final product (WM090TD) following production and after accelerated aging is documented in reports IANR23-022 and IANR24-013.
- VOC emissions testing of the final product following production and after accelerated aging is documented in reports IANR23-021, IANR23-028, and IANR24-013.

A summary and evaluation of these particulate matter and VOC emissions results are provided in the Biological Evaluation Report, pages 7–20. Overall, the biocompatibility evaluation addresses all relevant influences on product safety, including raw materials, manufacturing processes, aging, and packaging. The biocompatibility of WM090TD has been assessed using a combination of literature review and PM and VOC emissions test data, supporting the conclusion that the device is safe with respect to respiratory physiology and biocompatibility throughout its service life.

2. Is the polyether PU sound abatement foam subject to any processing or treatment? Please provide a flow chart of the foam manufacturing process.

With regard to the manufacturing process of the polyether polyurethane (PU) sound abatement foam, we would like to clarify that this is a commercially supplied, off-the-shelf material. The foam is used as received from the supplier and is not subject to any additional processing or treatment by us. The supplier considers the detailed manufacturing process to be proprietary and does not provide a manufacturing flow chart. Material suitability and consistency are ensured through supplier qualification, defined material specifications, and incoming material controls, including verification against agreed requirements and review of supplier documentation (e.g. material specifications and certificates of conformity). Based on these controls and the absence of any processing steps performed by us, a detailed manufacturing flow chart was not deemed necessary for the intended use of the foam within the device.

3. Were any particular risk control measures considered necessary as a result of the change in foam? Please provide an excerpt from the risk management file which addresses risks associated with the sound abatement foam.

Due to an identified risk of supply chain disruption, the foam was proactively replaced with an alternative polyether-based polyurethane foam. As part of the material change evaluation, a risk assessment was performed in accordance with our risk management process based on ISO 14971, taking into account the biological and chemical safety considerations outlined in ISO 10993-1 and ISO 18562-1.

No fundamental changes were made to the design, further properties or handling, except for the removal of a flame retardant. Therefore, no new hazardous situations were identified during the risk management review as a result of the change. However, the risk management team decided to repeat individual tests in order to continue verifying the effectiveness of existing risk control measures. As the flame retardant is no longer present in the foam, a test was carried out to examine the existing fire protection concept of the therapy device when using the new foams without flame retardants. Additionally, the testing of biocompatibility was repeated. Please find attached the respective excerpt from the risk management file.

4. In the investigation conducted on the device related to this incident, were any signs of degradation noted? Was the foam in the reported device specifically evaluated for degradation as part of your investigations?

In the course of our investigation of the prisma SMART max device associated with this incident, we conducted a thorough visual examination of the foam and all other internal parts relevant to potential material degradation. This assessment included the sound--abatement foam, structural housing elements, and the blower area, as these represent the locations where degradation would typically be detectable. During this inspection, no signs of degradation, abrasion, embrittlement, crumbling, or structural changes of the foam or any other device components were identified. All foam surfaces were intact and did not exhibit any changes consistent with chemical or mechanical breakdown.

To avoid any further destructive analysis, our investigation approach regarding the sound-abatement foam was visual and this method was considered fully appropriate and proportionate because the external analytical report performed on the substance found in the device clearly demonstrated that the collected residues were not related to any device material, including the polyurethane foam. Instead, the analysis determined that the substances consisted of organic compounds and trace elements consistent with environmental or user--derived substances, particularly residues typically associated with topical skin care products. The report confirmed the

absence of polymer--specific markers or any elemental profile indicative of polyurethane degradation. As such, there was no analytical indication that any internal component of the device, including the sound--abatement foam or the blower assembly, had deteriorated or contributed to the observed residue.

Given these findings, a more advanced or destructive material analysis of the foam was not warranted. The absence of any observable physical and chemical degradation, in combination with the conclusive analytical evidence excluding device materials as the source of the particles, provided a scientifically robust basis to determine that the foam was not implicated in this event. Therefore, no further investigation steps regarding foam degradation were required.

1.

5. Please also provide the raw data from the analysis conducted as part of your investigation of this incident on the residue detected on the foam and the air inlet.

The raw data from the analyses conducted during the investigation of the residue detected on the foam and the air inlet are provided as attachments. These data support the conclusions presented in our investigation report.

Should you require any further information, please do not hesitate to contact us. In addition, we would like to note that, should any aspect benefit from clarification in a phone call, our team remains available for a meeting at your convenience.

Thank you very much and best regards
[redacted]

Von: [redacted]
Gesendet: Freitag, 19. Dezember 2025 16:19
An: [redacted]
Betreff: RE: MHRA Ref: 2025/005/018/501/003_AW: Incident: Prisma SMART max CPAP

Dear [redacted]

Thank you for providing a response to the additional requests.

Upon review, I have some further queries for Löwenstein:

1. In your latest response to MHRA, you reference your material characterization results and the degradation and aging assessments. Please can you provide these?

2. Is the polyether PU sound abatement foam subject to any processing or treatment? Please provide a flow chart of the foam manufacturing process.

3. Were any particular risk control measures considered necessary as a result of the change in foam? Please provide an excerpt from the risk management file which addresses risks associated with the sound abatement foam.

4. In the investigation conducted on the device related to this incident, were any signs of degradation noted? Was the foam in the reported device specifically evaluated for degradation as part of your investigations?

5. Please also provide the raw data from the analysis conducted as part of your investigation of this incident on the residue detected on the foam and the air inlet.

It would be appreciated if we could receive a response during the first week of January 2026 to account for the holiday period.

Thank you in advance.

Regards

[redacted]

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From: [redacted]
Sent: 26 November 2025 09:46
To [redacted]
Cc: [redacted]
Subject: AW: MHRA Ref: 2025/005/018/501/003_AW: Incident: Prisma SMART max CPAP

Dear [redacted]

thank you very much for your additional requests. Please find below our responses:

1. MHRA notes that the device (WM100TD) subject to particulate matter testing and VOC testing is different to the device (WM090TD) in question. According to your BER, results from WM100TD are applicable given their similarities and WM100TD represents the worst-case scenario given that the gas pathway is larger. Does WM100TD contain the same sound abatement foam (polyether PU with a polyester PU film) and air filter as WM090TD?

Yes. Although the particulate-matter and VOC testing was performed on the WM100TD rather than the WM090TD, the results remain applicable because both devices use the same sound-abatement foam (polyether PU with a polyester PU film) and the same air-filter material. Therefore, with respect to materials that could contribute to particulate or VOC emissions, WM100TD is materially representative of WM090TD, and because WM100TD has the larger gas pathway, it can be considered the worst-case configuration for these assessments.

2. The BER provided seems to focus mostly on the 18562 series with some reference to ISO 10993-1. MHRA notes from your conclusion that In particular, no effects with regard to cytotoxicity, sensitization, irritation, systemic toxicity (acute and chronic toxicity), geno-toxicity, carcinogenicity, reproductive toxicity or implantation are likely. What information was used to draw this conclusion and were any other effects considered relevant given the materials and use of the device e.g. degradation?

The conclusion that no effects with regard to cytotoxicity, sensitization, irritation, systemic toxicity (acute and chronic toxicity), genotoxicity, carcinogenicity, reproductive toxicity, or implantation are likely is based on:

(1) the nature of patient contact for this device,
(2) material characterization results,
(3) the degradation and aging assessments conducted, and
(4) the VOC and particulate-matter evaluations performed according to ISO 18562.

(1) Relevant biological endpoints based on nature of contact

The WM090TD is a sleep-apnoea therapy device with two types of patient contact:

- Transient direct contact with touchable external components (e.g., device housing, user interface surfaces).

For these surfaces, only cytotoxicity, sensitization, and irritation would normally be considered. However, these components are made of well-characterised, widely used medical-grade polymers with no history of eliciting such effects, and no direct or prolonged patient contact occurs. Therefore, in accordance with ISO 10993-1, additional biological testing is not required. The materials used for these components are plastics that are commonly found in a wide range of everyday products and have been well-established in the market for many years. Typical applications include indoor and outdoor uses, such as

automotive parts, household appliances, and sports equipment, demonstrating their long-standing safe use.

- Indirect permanent contact through the breathing-gas pathway.

According to ISO 10993-1, this exposure type is assessed using the ISO 18562 series, which focuses on inhalation-related risks rather than direct-contact biological effects. Applicable endpoints therefore include:

• Acute and chronic systemic toxicity via inhalation
• Risks from inhaled volatile organic compounds (VOCs)
• Risks from inhaled particulate matter (PM)

Because no materials contact skin, mucosa, or blood directly for the duration required in ISO 10993-1, endpoints such as irritation, sensitization, cytotoxicity (direct contact), or implantation are not applicable for the breathing-gas pathway. Potential long-term endpoints, including carcinogenicity, genotoxicity, and reproductive toxicity, are evaluated through chemical characterization and inhalation-risk assessment per ISO 18562-1

(2) Materials and degradation considerations

All plastic and rubber components in the WM090TD are non-biodegradable, medical-grade polymers known for excellent resistance to temperature, oxidation, and chemical stress. Therefore, the inherent likelihood of degradation under normal use is very low. Nonetheless, aging effects were formally assessed:

- Accelerated aging, performed in accordance with ASTM F1980-21, using 78.5 days at 70°C and 95% RH to simulate real-time aging.
- These conditions represent a worst-case scenario intended to reveal potential release of VOCs, semi-VOCs, or particulate matter due to degradation.

(3) Polyether PU foam with polyester PU film

The device uses a polyether-based polyurethane sound-abatement foam with a polyester PU film, which has been specifically formulated to provide high chemical and mechanical stability. The aging behaviour of this foam type has been evaluated, and no indications of chemical or thermal degradation were observed. These foams have not been associated with material degradation under normal use conditions.

(4) VOC and particulate-matter testing, including aged devices

VOC and particulate-matter emissions were evaluated according to ISO 18562-1, -2, and -3. Testing was performed after accelerated aging, which represents a worst-case condition because higher temperatures promote release of potential degradation products. No substances indicative of thermal or chemical degradation of the foam or other components were detected in the VOC or PM measurements of aged devices. No emissions indicative of foam or component degradation were detected.

Basis for the conclusion regarding biological effects

The conclusion that no adverse biological effects are likely is supported by:

- The nature of exposure: transient direct contact for touchable components and indirect permanent contact via inhaled gas, consistent with ISO 10993-1
- Full conformity with ISO 18562, covering all relevant inhalation endpoints for breathing-gas pathway devices
- The inherent chemical stability of medical-grade, non-biodegradable polymers used in the device
- Accelerated aging data showing no release of degradation products
- VOC and PM measurements with no detectable degradation-related emissions
- Literature data and field-safety-notice reviews confirming that the polyether-based PU foam used in WM090TD is fundamentally different from - and more stable than - the polyester-based foam involved in known degradation issues

3. Lastly, the testing that has been conducted as part of the BER, was this conducted on the whole system? If so, please can you list each component subject to testing. Does this include a breathing mask or is this an off the shelf device?

The testing included in the Biological Evaluation Plan and Report was performed on the complete WM100TD device, as defined in the Biological Evaluation Plan (BEP), Chapter 1.3, which provides the full list of components included in the biological and ISO 18562 testing scope. This approach is consistent with ISO 18562, which requires assessment of the entire breathing-gas pathway rather than isolated materials.
The specific components subjected to VOC, particulate matter (PM), and material-characterization evaluations are those listed in BEP Chapter 1.3. These include the blower housing and internal airflow channels, the sound-abatement foam, and the air filter.
The breathing mask is not included in the BER for WM090TD, as it is an off-the-shelf accessory with its own regulatory conformity assessment and biocompatibility documentation.

If there are any further requests please don't hesitate to contact us.

Thank you very much and best regards

[redacted]

[redacted]
Löwenstein Medical Technology GmbH + Co. KG
Kronsaalsweg 40
Hamburg Germany
loewensteinmedical.com

Von: [redacted]
Gesendet: Donnerstag, 20. November 2025 16:17
An: [redacted]
Cc: [redacted]

Betreff: RE: MHRA Ref: 2025/005/018/501/003_AW: Incident: Prisma SMART max CPAP

Dear [redacted]

Thank you for your email and providing the requested documents, as well as clarification on the device details.

I have a few additional follow-up questions regarding the BER:

1. MHRA notes that the device (WM100TD) subject to particulate matter testing and VOC testing is different to the device (WM090TD) in question. According to your BER, results from WM100TD are applicable given their similarities and WM100TD represents the worst-case scenario given that the gas pathway is larger. Does WM100TD contain the same sound abatement foam (polyether PU with a polyester PU film) and air filter as WM090TD?

2. The BER provided seems to focus mostly on the 18562 series with some reference to ISO 10993-1. MHRA notes from your conclusion that *In particular, no effects with regard to cytotoxicity, sensitization, irritation, systemic toxicity (acute and chronic toxicity), geno-toxicity, carcinogenicity, reproductive toxicity or implantation are likely*. What information was used to draw this conclusion and were any other effects considered relevant given the materials and use of the device e.g. degradation?

3. Lastly, the testing that has been conducted as part of the BER, was this conducted on the whole system? If so, please can you list each component subject to testing. Does this include a breathing mask or is this an off the shelf device?

It would be appreciated if you can provide a response by 26/11/2025.

Thank you in advance.

Regards

[redacted]

[redacted]

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

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From: [redacted]
Sent: 13 November 2025 15:49
To: [redacted]
Cc: [redacted]

Subject: AW: MHRA Ref: 2025/005/018/501/003_AW: Incident: Prisma SMART max CPAP

Dear [redacted]

[redacted]

Please find attached the requested ISO 18562 analysis reports as specified in the Biological Evaluation Report. Additionally, please find attached the toxicological evaluation. For your information, personal data of Löwenstein Medical Technology employees have been redacted.

The Biological Evaluation Report and the corresponding Biological Evaluation Plan were already provided to the MHRA on 01-Sep-2025.

For confirmation, the device used for investigation and testing was the actual complaint device. The details you provided below are correct, with the exception of a minor discrepancy in the medical device name: the correct name is WM090TD, not WMTD90.

If you have any further requests, please don't hesitate to contact us.

Thank you very much

Best regards,

[redacted]

Von: [redacted]
Gesendet: Mittwoch, 12. November 2025 14:30
An: [redacted]
Cc: [redacted]

Betreff: RE: MHRA Ref: 2025/005/018/501/003_AW: Incident: Prisma SMART max CPAP

Dear [redacted]

Thank you for your email.

[redacted]

Apologies for any confusion in my previous email. For clarification, regarding the device used in testing and referenced in the investigational summary report, could you please confirm that the device was the patient's device for which we have the following details:

Medical device name: Prisma SMART max CPAP (WMTD90)

UDI device identifier: 04050384301282

Basic UDI-DI: 4050384WM090TDGN

Serial number: 26739107

Please provided a response by 14/11/2025.

Thank you in advance.

Regards

[redacted]

[redacted]

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From: [redacted]
Sent: 10 November 2025 16:56
To: [redacted]
Cc: [redacted]
Subject: AW: MHRA Ref: 2025/005/018/501/003_AW: Incident: Prisma SMART max CPAP

Dear [redacted]

thank you very much for your additional requests and your patience in this matter.

I respond to your email of 6th November on behalf of [redacted]. Please find below the requested information.

The UDI 4050384WM090TDGN mentioned above is the basic UDI-DI. This Basic UDI Device Identification is the primary identifier of the product or product group in question. In this case, the UDI 4050384WM090TDGN identifies the product as WM090TD.

All tests were performed on the product in question in accordance with IMDRF Code Appendix B01.

Additionally, you asked for the time stamped photos that were included in the investigational summary report. Some images in the report are excerpts from the original photos. The original files of the requested images are attached to this mail. The recording date is indicated in the picture details.

We are pleased to provide you with the requested 18562 test reports along with the biological evaluation report. [redacted]

Thank you very much for your understanding and best Regards

[redacted]

Von: [redacted]
Gesendet: Donnerstag, 6. November 2025 13:38
An: [redacted]
Cc: [redacted]
Betreff: RE: MHRA Ref: 2025/005/018/501/003_AW: Incident: Prisma SMART max CPAP

Dear [redacted]

Thank you for your email and redacted email correspondence PDF. As requested, this will be shared with the applicant of the FOI request.

Please can I have an update on the request for the test reports and request these are provided to MHRA by 10/11/2025. As a reminder, I previously asked Lowenstein to provide the following:

1. all 18562 test reports

2. full biological evaluation report in line with ISO 10993-1 including any biological test reports

In addition, I have a couple of follow-up queries for Lowenstein:

- Please clarify if UDI 4050384WM090TDGN was the device tested as per the investigation summary report?

- Provide time stamped photos of the photos included in the investigational summary report.

Please respond and provide all the requested information by 10/11/2025.

Thank you in advance.

Regards

[redacted]

Medicines and Healthcare products Regulatory Agency
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