Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00488**

02 June 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 4 May. You wrote:

I request information under the Freedom of Information Act 2000 relating to MHRA's assessment of the Löwenstein prisma SMART max (WM090TD), specifically the statement communicated to me that the foam/material is "not the same" as that implicated in the Philips PE-PUR recall.

This request is limited to recorded information held by MHRA at the date of search.

1) Basis and timing of MHRA's "not the same foam" position
Please provide any recorded information that states or explains:

* *the basis for MHRA's conclusion that the foam/material in WM090TD is not the same as the Philips PE-PUR foam; and*
* *the date(s) when this position was formed, reviewed, or communicated internally.*

This may include internal notes, summaries, emails, or correspondence referring to that conclusion.

2) Evidence relied upon
Please provide any recorded information identifying the type of evidence MHRA relied upon to reach that conclusion, for example:

* *manufacturer statements or declarations;*
* *notified body statements;*
* *material descriptions or datasheets;*
* *test evidence identifiers (e.g., ISO 18562 reports), if referenced.*

(Where documents are exempt in full, please provide titles/identifiers and dates, with redactions as appropriate.)

3) Assessment scope (device-specific vs model-level)
Please confirm whether MHRA holds any recorded information showing that:

* *the assessment was device-specific (e.g., linked to a serial/lot/UDI-PI), or*
* *the assessment was conducted at model/family level only.*

If held, please provide the recorded confirmation.

4) Foam/material change timing and implementation
In light of information indicating a material/foam change (e.g. Polyester-polyurethane to Polytethylene-polyurethane) around late September 2024, please confirm whether MHRA holds any recorded information on:

* *change-control initiation/approval date(s);*
* *implementation/effective date(s);*
* *affected serial/lot/UDI-PI ranges;*
* *any statement of from which point in 2024 devices would contain the new material.*

If held, please provide the recorded information (redacted as necessary).

5) Inter-regulator communications
Please confirm whether MHRA holds any recorded correspondence or notes of communication with other regulators (including the Therapeutic Goods Administration) relating to:

* *the foam/material used in WM090TD; or*
* *the assessment that it is "not the same" as Philips PE-PUR.*

If held, please provide such records (with appropriate redactions).

6) Market actions relating to earlier material configuration
Please confirm whether MHRA holds any recorded information indicating:

* *whether devices with any earlier foam material configuration (prior to the 2024 change), that had the same foam or similar from the same or similar manufacturer of the foam, as a result of Philips CPAP medical devices recall due to PE-PUR Foams were withdrawn, restricted, or subject to corrective action in the UK; and*
* *if not, any recorded rationale for no withdrawal/restriction in the context of industry concerns about foam degradation.*

7) Breathing gas pathway / ISO 18562 evidence (identifiers only)
Please confirm whether MHRA holds recorded identifiers for any ISO 18562 (or equivalent) evidence relied upon for this device family, including:

* *report title/identifier and date/version;*
* *whether the evidence related to WM090TD specifically or a representative model;*
* *whether the test boundary was device-only or system-level (device + tubing/mask/interface).*

(I am not requesting full confidential reports, only identifiers/scope information where held.)

MHRA Response

For ease, we will address each of the items individually:

1) Basis and timing of MHRA's "not the same foam" position
Please provide any recorded information that states or explains:

* *the basis for MHRA's conclusion that the foam/material in WM090TD is not the same as*

the Philips PE-PUR foam; and

* *the date(s) when this position was formed, reviewed, or communicated internally.*

This may include internal notes, summaries, emails, or correspondence referring to that conclusion.

The Agency has completed a search of its records and confirms that information within scope of your request is held.

We are releasing the information that can be disclosed. Some material has been redacted under Section 40(2) of the Freedom of Information Act (FoI), as it contains personal data. Disclosure of this data would breach data protection principles, specifically the requirement for personal data to be processed lawfully, fairly, and in a transparent manner.

The releasable information is provided in the attached document (Ref: email correspondence (1)). This material was also previously provided to you under FOI2025/00879.

The records include correspondence setting out the MHRA's position that the foam/material used in WM090TD device differs from the Philips PE-PUR foam. Specifically, this position is derived from correspondence between the MHRA and Löwenstein Medical dated 5th August 2025, in which the manufacturer describes the type and composition of the foam used in WM090TD device. This information forms the basis for the MHRA's understanding of the material used and underpins the comparison with the foam type identified in Philips devices.

2) Evidence relied upon
Please provide any recorded information identifying the type of evidence MHRA relied upon to reach that conclusion, for example:

* *manufacturer statements or declarations;*
* *notified body statements;*
* *material descriptions or datasheets;*
* *test evidence identifiers (e.g., ISO 18562 reports), if referenced.*

(Where documents are exempt in full, please provide titles/identifiers and dates, with redactions as appropriate.)

We confirm that relevant information is held by the MHRA regarding the types of evidence used to inform its position. However, some of this information is:

- withheld under Section 41(1) (information provided in confidence)
- publicly available (Section 21(1))

Reports pertaining to ISO 18562 were obtained from a third party and are withheld under Section 41(1), as disclosure would constitute a breach of confidence.

The test report identifiers are as follows:

- IANR23-022_v01
  ISO 18562 Biocompatibility evaluation of breathing gas
  pathways in healthcare applications
  Part 2: Tests for emissions of particulate matter

- IANR23-028_v02
  ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications
  Part 3: Tests for emissions of volatile organic compounds (VOCs)

- IANR23-021_v01
  ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications
  Part 3: Tests for emissions of volatile organic compounds (VOCs)

- IANR24-013_v01
  ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications
  Part 2: Tests for emissions of particulate matter
  Part 3: Tests for emissions of volatile organic substances

Further information is exempt under Section 21(1), as it is reasonably accessible in the public domain and provides background on the foam used in affected Philips devices.

To assist you, relevant information can be found here:

Philips Field Safety Notice (2021):
https://mhra-gov.filecamp.com/s/o/gLAqe1qzwVtm1jGJ/CZ9MInEuPJpQ27uN/MdNreZac73sH0WgV

This notice describes the PE-PUR foam used in affected Philips devices.

In addition, MHRA records (previously provided under FOI2025/00879) indicate that:

- The foam used in the Löwenstein prisma SMART max WM090TD (UK-supplied units) is polyurethane foam based on polyether
- The foam has a thin polyurethane outer layer based on polyester
- The core sound abatement material is not polyester-based polyurethane

Further relevant context is included in the material released under Question 1.

In summary, MHRA's conclusion that the foam/material used in the WM090TD device is "not the same" as that implicated in the Philips PE-PUR recall, is derived from a comparison between:

- the foam specification described in the Philips Field Safety Notice (2021); and
- manufacturer-provided information from Löwenstein describing the foam composition used in the WM090TD device,

together with supporting biological evaluation documentation (e.g. Biological Evaluation Plan and Biological Evaluation Report) supplied by the manufacturer.

This comparison indicates that the core sound abatement material used in the WM090TD is polyether-based polyurethane, rather than the polyester-based PE-PUR foam identified in the Philips devices.

3) Assessment scope (device-specific vs model-level)
Please confirm whether MHRA holds any recorded information showing that:

* *the assessment was device-specific (e.g., linked to a serial/lot/UDI-PI), or*
* *the assessment was conducted at model/family level only.*

If held, please provide the recorded confirmation.

We confirm that the MHRA holds information on the scope of the assessment.

The releasable information is attached to this response (Ref: email correspondence (2)) and was previously provided under FOI2026/00048.

This documentation indicates how the assessment was conducted, including whether it was performed at device-specific or model/family level.

4) Foam/material change timing and implementation
In light of information indicating a material/foam change (e.g. Polyester-polyurethane to Polytethylene-polyurethane) around late September 2024, please confirm whether MHRA holds any recorded information on:

* *change-control initiation/approval date(s);*
* *implementation/effective date(s);*
* *affected serial/lot/UDI-PI ranges;*
* *any statement of from which point in 2024 devices would contain the new material.*

If held, please provide the recorded information (redacted as necessary).

Following a search of our records, we confirm that this information is not held by the MHRA.

Information such as:

- change-control dates
- implementation dates
- serial/lot/UDI ranges

is typically held by the manufacturer or the notified body responsible for conformity assessment, rather than by the MHRA.

5) Inter-regulator communications
Please confirm whether MHRA holds any recorded correspondence or notes of communication with other regulators (including the Therapeutic Goods Administration) relating to:

* *the foam/material used in WM090TD; or*
* *the assessment that it is “not the same” as Philips PE-PUR.*

If held, please provide such records (with appropriate redactions).

We confirm that the MHRA holds relevant communications with other regulators.

The releasable information is attached (Ref: TGA email) and was previously provided under FOI2025/01140. Any necessary redactions have been applied in accordance with FOI exemptions.

The following link, cited by TGA in the email, takes you to a post-market review of ventilator, CPAP and BiPAP devices on the Australian market where you can find lists of devices containing PE-PUR foam or other types of materials:
https://www.tga.gov.au/safety/safety-monitoring-and-information/medical-device-post-market-monitoring-and-safety-updates/post-market-review-ventilator-cpap-and-bipap-devices

6) Market actions relating to earlier material configuration
Please confirm whether MHRA holds any recorded information indicating:

* *whether devices with any earlier foam material configuration (prior to the 2024 change), that had the same foam or similar from the same or similar manufacturer of the foam, as a result of Philips CPAP medical devices recall due to PE-PUR Foams were withdrawn, restricted, or subject to corrective action in the UK; and*
* *if not, any recorded rationale for no withdrawal/restriction in the context of industry concerns about foam degradation.*

Following a search of our records, we confirm that the MHRA holds information relevant to your request.

Some information is:

- publicly available (Section 21(1))
- withheld under Section 41(1) (information provided in confidence)

Relevant public information can be found in the National Patient Safety Alert (23 June 2021):
https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-philips-ventilator-cpap-and-bipap-devices-potential-for-patient-harm-due-to-inhalation-of-particles-and-volatile-organic-compounds-natpsa-slash-2021-slash-005-slash-mhra

Following this alert, MHRA worked with manufacturers to implement risk mitigation measures for devices placed on the UK market.

However, further information you requested, specifically whether particular devices were withdraw or restricted, and the rationale for any such decisions – was obtained from third parties and is withheld under Section 41(1), as disclosure would constitute a breach of confidence.

7) Breathing gas pathway / ISO 18562 evidence (identifiers only)
Please confirm whether MHRA holds recorded identifiers for any ISO 18562 (or equivalent) evidence relied upon for this device family, including:

* *report title/identifier and date/version;*
* *whether the evidence related to WM090TD specifically or a representative model;*
* *whether the test boundary was device-only or system-level (device + tubing/mask/interface).*

We confirm that the MHRA holds information within the scope of your request.

Some information has been released and is included in the material referenced in response to Question 3.

However, the full reports and detailed technical content are withheld under Section 41(1) of the Freedom of Information Act. This exemption applies to information provided to the MHRA in confidence by third parties (e.g. manufacturers), where disclosure would constitute an actionable breach of confidence.

Despite this, we are able to provide the following high-level identifiers and document details, as requested:

1. **Biological Evaluation Plan**

   - Document title: BEP_WM090TD_Rev02
   - Revision: 02
   - Date: 26 November 2024

2. **Biological Evaluation Report**

   - Document title: BER_WM090TD_Rev02
   - Revision: 02
   - Date: 26 November 2024

These identifiers correspond to the biological evaluation documentation for the WM090TD device family.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information