



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](#)

Our Ref: **FOI2025/00897**

7 November 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 24 August. You wrote:

This is a new, narrow FOI request.

Timeframe: 1 Jan 2024 – present

Product: Löwenstein prisma SMART max WM090TD (UK-supplied units only)

Please provide final copies or single-page system extracts (redactions welcome) of the following, held by MHRA:

The earliest and/or latest record MHRA holds that identifies the production identifier(s) for the design change to the sound-abatement foam in WM090TD supplied in the UK — e.g., the first affected or from-this-point serial number / lot / manufacture date / UDI-PI notified to MHRA by the UK Sponsor/Authorised Representative.

The UDI identifiers for WM090TD on the UK database (the Basic UDI-DI and UDI-DI(s)) and the effective date MHRA recorded for the configuration that reflects the changed foam material. A single database screenshot or export is fine.

The closing note/minute (one page) of MHRA's device-change entry for WM090TD confirming that the foam design change notification was recorded/closed and the date that entry was closed.

MHRA Response

Following a search of our paper and electronic records, we have established that the information you requested is not held by this Agency. This is information that is typically held by the approved or notified body awarding the conformity certification for the medical device.

Further to your previous FOI request: FOI2025/00774, and to assist with this request, it may be helpful if we share information and correspondence from the manufacturer that we hold, regarding the *Löwenstein Medical prisma SMART max WM090TD (UK-supplied units only)* device and the sound abatement foam.

The sound abatement foam used in the *Löwenstein Medical prisma SMART max WM090TD (UK-supplied units only)* device consists of a polyurethane foam based on **polyether**, not polyester. The foam is covered with a thin polyurethane skin, which is based on polyester, the core sound abatement material itself is not polyester-based polyurethane. Please see the

enclosed correspondence from the manufacturer Löwenstein Medical attached to the end of this response.

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.

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>

Enclosure: Email correspondence between MHRA and Löwenstein Medical

Von: Vigilance <vigilance@loewensteinmedical.com>

Gesendet: Dienstag, 5. August 2025 15:53

An: [REDACTED]

Cc: [REDACTED]

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

Dear [REDACTED],

[REDACTED]

[REDACTED]

[REDACTED]

- Regarding your last comment, "Details on the material used in the sound abatement foam. Is this a polyester-based polyurethane foam?", I can provide the following information:

- No, the sound abatement foam in our device consists of a polyurethane foam based on polyether, not polyester. The foam is covered with a thin polyurethane skin, which is based on polyester, to provide surface sealing while remaining permeable to sound. Therefore, the core sound abatement material itself is not polyester-based polyurethane.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]