

Epilium & Skin Ltd

Epilium & Skin

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location

Inspected but not rated



Are services safe?

Inspected but not rated



Are services effective?

Inspected but not rated



Are services well-led?

Inspected but not rated



Summary of findings

Overall summary

The service Epilium & Skin provides surgical procedures to adults only. We inspected the service using our focused inspection methodology.

This inspection was a focused follow up inspection to review if all areas of concern raised at our previous inspection in December 2022, had been resolved and the risk of harm to patients had been removed. We did not rate the service at this inspection; we were following up on concerns raised at our previous inspections.

We found:

- The service did not follow required legislation in relation to recruitment or registration of staff providing regulated activities.
- There were no medicines management systems in place. There was no stock control system in place.
- The service did not monitor the effectiveness of care and there was no system to ensure the competence of staff.
- Governance systems were not functioning, and the provider did not have a good understanding of the service or their responsibilities in relation to risk and leadership.

Following our comprehensive inspection in December 2022, the service was rated inadequate, we suspended the registration of the provider and placed the service into special measures.

Following the focused follow up inspection, suspension of the regulated activities was extended for a further eight weeks because the service had not made all the required improvements.

Services placed in special measures will continue to be monitored. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling the registration or to varying the terms of their registration within six months if they do not improve. Where necessary another inspection will be conducted within a further six months, and if there is not enough improvement, we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	Inspected but not rated	



Summary of findings

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Summary of this inspection

Background to Epilium & Skin

Epilium & Skin is operated by Epilium & Skin Ltd. The service provides private cosmetic treatments from clinical premises which are also used for unregulated aesthetic treatments. The clinic offered treatments such as blepharoplasty (eyelid reduction), labiaplasty (labia minora reduction), gynecomastia (male chest lift), fat transfer, and hair transplant. The service has one operating theatre, one recovery room, one consultation room and a waiting area. Procedures were carried out under local anaesthetic and conscious sedation only.

The provider registered this location in January 2011. A registered manager was in post and the service was registered to carry out the following regulated activity:

- Surgical procedures

How we carried out this inspection

We carried out an unannounced inspection using our focused inspection methodology of the service on 28 February 2023. Our inspection team consisted of a lead inspector and an inspection manager.

After our inspection we asked the provider to send us additional data relating to two patients. They did not provide us with all of the information we requested.

You can find information about how we carry out our inspections on our website: <https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection>.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations.

Action the service MUST take to improve:

- The service must ensure decontamination facilities or decontamination services are available to ensure the safe use of surgical equipment. (Regulation 12)
- The service must implement and maintain consistent, safe medicines management. This must include safe procedures in line with national requirements that include storage, stock management, prescribing, administration, and destruction. (Regulation 12)
- The service must ensure medical emergency equipment is available and maintained. (Regulation 12)
- The service must implement clinical monitoring and outcome processes. (Regulation 12)
- The service must ensure it fully complies with Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 in relation to the safe recruitment of staff. (Regulation 12)
- The service must ensure clinical governance processes are fit for purpose, contribute to the safe running of the service and enable the registered manager to gain assurance that risk and performance is managed effectively. (Regulation 17)




Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated
Overall	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated

Surgery

Safe	Inspected but not rated 
Effective	Inspected but not rated 
Well-led	Inspected but not rated 

Is the service safe?

Inspected but not rated 

We did not rate safe during this inspection.

Cleanliness, infection control and hygiene

The service could not evidence they controlled infection risk well. Not all equipment was clean.

We found needles and used broken ampules used for unregulated dermatology procedures stored in a tray with a variety of medicines and dermatology products that were partially used. Bottles were sticky and visibly dirty. After the previous inspection the registered manager told us the issues relating to the storage and use of part used medicines and equipment had been resolved. We found they had not been resolved during our focused follow up inspection.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not always keep people safe.

There were still no decontamination facilities for surgical equipment and staff were unable to explain how reusable equipment was cleaned ready for use. There were still no audit records to provide assurance of such processes were in place.

The service had purchased a suction machine since the previous inspection. However, the suction machine purchased was not suitable for the requirements of a theatre undertaking the procedures the service offered. The machine required plugging in to the wall and had a very short electrical cord attached. Service users may be exposed to the risk of harm due to the lack of suitable equipment as it would not be possible to clear their airway. A suction machine, or aspirator, removes obstructions such as mucus or blood from a person's airway. The device is an important part of surgical safety.

The service had purchased a blood pressure monitoring machine which was a home use monitor and did not fit the various size cuffs required for the range of patients that would be seen by the service. Some of the cuffs we found in the resuscitation trolley could not be connected to the blood pressure machine because they were for a different model of machine and did not have the correct connector.

Emergency medical equipment remained unfit for purpose. The service had a resuscitation trolley that remained unsecured and was used to store non-emergency medicines and equipment. This meant access to emergency medicines and equipment may be delayed as these were not stored in a designated trolley ready for immediate access. This demonstrated the service still did not have an understanding of what emergency medical equipment and medications were required and that should only be held in the resuscitation trolley.

Surgery

There was not enough equipment to provide emergency care in the event a patient deteriorated. The emergency trolley still did not have enough equipment for staff to use in an emergency. For example, only 1 laryngeal airway mask in the resuscitation trolley. This was suitable only for patients who weighed between 50 – 70kg and would not support patients outside of this range.

There was a bag valve mask situated on top of the resuscitation trolley, it had tubing, and a mask attached but they were not stored in a bag to protect from dust.

There were still a considerable number of consumables which were out of date. Some which went out of date prior to the previous inspection and others which had gone out of date since the previous inspection. This demonstrated the service still did not have an effective stock management process in place.

The service was still not undertaking or documenting the checking of the ambient temperature in the theatre where medication was being stored. Some medication we saw was required to be stored below 25 degrees, the service was not able to provide assurance that the temperature of the theatre has not exceeded 25 degrees. Therefore, the effectiveness of the medication could not be assured as it had not been stored in line with manufacture's guidance.

The Controlled Drug (CD) cabinet was located in an unlocked cupboard above a hand washing sink in the theatre. This arrangement was not in line with national requirements for the CD cabinet to be inside a locked cupboard. The CD cabinet was empty with a CD register stored on top of the cabinet.

Assessing and responding to patient risk

Staff did not complete risk assessments for each patient. There was no policy for staff to identify and act upon patients at risk of deterioration. The service did not make sure patients knew who to contact to discuss complications or concerns.

The service did not have assurance staff used a nationally recognised tool to identify deteriorating patients and escalate them appropriately. While regulated care was not being undertaken at the time of our inspection, patient records, for procedures undertaken prior to our inspection, did not include evidence of pre-surgery risk assessments or the use of a tool to monitor each patient's condition during surgery.

Pre-surgical records required patients to self-disclose their medical history and any risk issues. However, there was no documented evidence staff assessed these and adjusted clinical care accordingly.

There was still no risk assessment or inclusion/exclusion criteria in place that enabled staff to identify if a patient was unsuitable for cosmetic surgery. This presented a risk to safety because it meant staff had not assessed patients' known health issues, including mental health needs, prior to carrying out surgery. The registered manager had informed us prior to the follow up inspection that this had been written and put in place, but we could find no evidence of it during the inspection and staff we asked could not show this to us.

The service still did not have a standard operating procedure for the management of patients who deteriorated. There was no guidance for the actions staff should take if a patient deteriorated or the threshold at which staff would arrange an urgent transfer to another facility or call 999. Staff said there had been discussions about this, but no policy was yet in place. The registered manager had informed us prior to the follow up inspection that this procedure had been developed. Staff we asked during the inspection could not show us this document.

Surgery

Staffing

The service could not evidence it had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

The service did not employ nurses or healthcare support workers. Doctors and surgeons working under practising privileges brought their own theatre support staff with them on operating days. However, the service still did not have a process to keep records of these staff and therefore, were unable to confirm if they these staff were trained, accredited professionals.

We reviewed the files for seven doctors, six of which were surgeons, and one was a dermatologist, who had a practising privilege agreement with the provider and were able to deliver regulated activities. While they held approval that allowed them to practice, they rarely delivered care in the clinic. We found none of the files had a full complement of the required documentation relating to employment and expected standards of each doctor. We found two of the seven doctors did not have a Designated Body. The service had not obtained suitable references for all seven of the doctors with practising privileges. The references which we noted in the files held by the service were not on headed paper and were mostly personal references. They did not provide satisfactory evidence of conduct in previous employment as required by the regulation. Prior to the inspection, the registered manager had confirmed by email that they had withdrawn practising privileges for one of the doctors but the file we reviewed at the service did not have any evidence to support this.

The service's website still listed 3 other doctors as providing care and instructions of how to book appointments with these individuals. However, the clinic manager told us none of these staff were currently providing care. Therefore, information available to the public to inform their choice of doctor was not an accurate picture of the range of services and doctors available at the service.

During the follow up inspection we found that for the employed member of staff, there were no application form or CV on file. There was no record of an interview having taken place. There was also no evidence of right to work in the UK or references on file.

These lack of pre-employment checks and accurate up to date staff information on file demonstrated that the provider still did not understand their responsibility in relation practising privileges, recruitment of staff and need to ensure records were kept of who was working in their service.

Records

Staff kept inconsistent records of patients' care and treatment. Records were not always clear, up-to-date, or stored securely.

Some of the patient notes we found were stored in hard copy in various files in a cupboard in the theatre. There was no tracking system and the service still had not established a system to maintain an overall record or archive of patient care and treatment. Therefore, the registered manager did not have assurance of patient safety or care and treatment outcomes.

We found two surgical consent forms, for two different patients, which were dated on two separate dates during the time the service was suspended from undertaking the regulated activity of surgical procedures. We requested the full patient notes for the two patients. We received brief notes for one patient and the service stated that the procedure had taken place in another clinic not associated with them. But no evidence was provided to confirm this. We did not receive the second set of notes despite making a further request to the registered manager. There was no evidence provided to demonstrate that these procedures had not taken place at the service during the suspension.

Surgery

Medicines

The service did not have systems and processes to safely prescribe, administer, record and store medicines.

There was still no medicines management system in place. Medicines were stored in various drawers, cupboards, and trolleys. There was no stock control or tracking system. While access to the theatre was controlled with a coded, locked door, medicines were not stored in locked cabinets. This was not in line with national best practice.

Staff did not follow systems and processes to prescribe and administer medicines safely. We saw evidence that the service was in the process of ordering morphine, which is a controlled drug. However, the service does not hold a controlled drugs licence from the Home Office. We saw evidence that during 2019 the service had held and dispensed a controlled drug to a patient. The service did not hold a controlled drugs licence from the Home Office at this time. We were told the plan was for doctors to continue to bring their own medicines to the clinic, including controlled drugs (CDs). However, the service still did not have a standard operating procedure in place for this. The service still had not developed a process to keep a record of the medicines brought on site and who prescribed them. There was also no process for how any unused CDs would be disposed of.

A medicine which the service was using for unregulated activities was held in a cupboard in the operating theatre, the label was not in English. The packaging and internal leaflet did not follow the legal requirement for a medicinal product. The packaging and information leaflet were not in English, and we could see no manufactures licence to confirm this overseas product could be used in the UK.

The resuscitation trolley held medicines which were not required for use in an emergency situation. The service was using the resuscitation trolley as a medicine's storage area. We found Voltarol ampoules 75 mgs/3ml, Lidocaine Hydrochloride 2% w/v solution for injection, Flumazenil 0.1mg/ml injection, Medrone tablets 16mg and water for injection 100% w/v 1ml stored on the resuscitation trolley alongside medicines that would be required in an emergency situation.

We found medications which staff told us were being used by the dermatologist for non-regulated activities, stored in a tray in a cupboard in theatre. In the tray were part used vials of injectable medications, broken used ampoules, used syringes and a stained and dirty bottle of topical serum. This demonstrated there were no systems and processes in place to ensure used medicines and syringes were disposed of in line with best practice.

Is the service effective?

Inspected but not rated 

We did not rate effective during this inspection.

Competent staff

The service did not have a system to make sure staff were competent for their roles. Managers did not appraise staff's work performance or hold supervision meetings with them to provide support and development.

We saw no evidence still that staff had participated in an annual appraisal. There was still no record of appraisals for any of the surgeons with practising privileges within the last 5 years.

There was still no evidence permanent support staff had undertaken developmental opportunities or continuing professional development.

Surgery

Is the service well-led?

Inspected but not rated 

We did not rate well led during this inspection.

Leadership

Leaders did not have the skills and abilities to run the service. They failed to understand and manage the priorities and issues the service faced.

The managing director was the registered manager. We saw no evidence the registered manager understood the level of concern raised during the previous inspection. The registered manager wrote to us following the inspection to provide assurance that many areas of concern had been addressed. However, when we inspected the service, we found that these areas had not been addressed or in fact some of the solutions put in place or actions taken had actually created further risks for patients and the service. The clinic manager was a non-clinical member of staff who was trying to make improvements, but they did not have the skills, or the knowledge required. The director was based substantively outside the UK and a clinic manager was responsible for the day-to-day operation of the clinic, including unregulated services.

We remain unassured of the abilities of the registered manager and clinic manager. There were still gaps in understanding of governance, operational safety, and the measures needed for safe clinical practice. Leaders still could not evidence they understood challenges to quality and sustainability. They still had not acted substantively to address quality issues.

The service still did not have a system to ensure staff and those working under practising privileges were supported with performance, met and trained together, and had access to human factors training to underpin the delivery of safe care. This would usually be included in work to follow the National Safety Standards for Invasive Procedures (NatSSIPs), but the service did not take part.

As part of our inspection process, we issued the provider with a request for specific data. We did not receive all the data we requested despite asking the registered manager for it on two occasions, we finally only received the information after sending a legal request to the registered manager.

Governance

Leaders did not operate functioning governance processes.

The governance system remained not fit for purpose. The provider and registered manager were not compliant with their regulatory responsibilities and did not have processes in place to ensure safe standards of working.

The service still did not have a deteriorating patient policy or an admissions and exclusion criteria policy in place. The registered manager had assured us they had developed an admissions and exclusion criteria but there was no evidence of this during our inspection.

Management of risk, issues and performance

There was no system to manage performance effectively.

Surgery

The service still did not have comprehensive assurance systems in place and there were no processes to monitor cosmetic surgery services. The service did not have systems for continuous improvement in infection prevention and control. This lack of systems meant that patient safety risks would not be mitigated or avoided.