**Information for manufacturers of TheatreCapChallenge hats**

**This information is intended to be helpful. There is more on the** [**www.mhra.gov.uk**](http://www.mhra.gov.uk) **website.**

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# **Information for manufacturers of cloth theatre hats**

## Is a cloth Theatre cap a Class 1 Medical device?

The Medical Devices Regulations and the [www.mhra.gov.uk](http://www.mhra.gov.uk) website are helpful. Cloth theatre hats may be viewed as a medical device. The hat has several uses:

* It is personal protective equipment (not a medical device, but does also have to comply with the Health and Safety at Work Act) and
* It is to protect patients, by protecting patients from staff members’ heads (like all theatre hats and surgical masks that are already medical devices) and to protect the patient from errors of misidentification

Although the hat in use has a medical purpose, it is not necessarily the manufacturer that gives it this purpose.

There seem to be two options:

1. If a manufacturer markets their hats with no medical purpose or claim, then they can continue. Eg they may say they are just hats for making you look nice. Hospital Trusts are also free to buy these and use them for medical purposes, and the Hospital Trust accepts the risk.
2. If a manufacturer wishes to market their hats with a medical purpose, they should register with MHRA. This costs around £100. You put a CE mark on all the products. Information about how to do this is in the rest of this document. Most information can be cut and pasted. Some manufacturing details are also needed. Records need to be kept. MHRA will be contacting manufacturers who make a medical claim for their product who are not registered.
3. Hospital Trusts can choose to purchase hats and use them for any purpose. They should undertake a risk assessment if they are using the hat for a medical purpose. They are often slow to take up change or new initiatives and are often risk averse. It is possible that a Hospital Trust would be more likely to choose a manufacturer with a registered product with a CE mark.

## More detail about MHRA involvement and whether to register as a manufacturer of a Medical Device

There are large numbers of operating theatre staff and organisations around the world keen to support the #TheatreCapChallenge, wearing personalised re-useable cloth hats in the operating theatre and similar environments, often with name and rank embroidered or written on the hat to help team working.

There are some practicalities to consider. There are good studies showing that these hats reduce infection problems and cause fewer surgical site infections in patients. Other studies show the importance of team communication and of clarity about someone’s name and role.

It is possible that a cloth Theatre Cap could be considered as a medical device. One reason it is used is to protect the patient from the staff-member’s hair or dandruff. Whether it is or not, depends on what claims the manufacturer makes. There appear to be two options:

* The regulations are there to ensure that patients are protected by only being exposed to safe medical devices, so complying with the regulations will make your hats safer and therefore better. Once this is done, this can be used in advertising, that it is a demonstrably safe and regulated device. If the manufacturer makes any medical claim that the hat is intended to protect patients for use in the operating theatre or similar health environment, the manufacturer needs to register with the MHRA. If it is a medical device, the manufacturer needs to register with the Medical Devices Agency (MHRA), supply details and keep records. Each hat can be approved and have a CE mark. (This document gives detailed suggestions on how to register and MHRA is helpful.) It may be that larger manufacturers wish to register. **OR:**
* It is possible that some manufacturers could market their hats on the basis that they are just hats for making you look nice, i.e. there is no medical purpose to the hat. If they say this and do not make any medical claim for the hat, then they do not have to CE mark the hat as complying with the Medical Device Regulations. The hospital or an individual is also free to buy these and use them for medical purposes, which means that they accept the risks associated with that. In this case, this risk assessment would be fairly easy for a hospital to do and they would accept the risk. The MHRA have suggested that some manufacturers seem not to be making a medical claim and may choose to carry on their business that way: that is fine. Some seem to be making a medical claim and not to be registered with MHRA, so will be contacted to that effect. They may choose to remove the medical claims or to register with MHRA.

# “Not made with Natural Rubber Latex” if possible

It would seem sensible for manufacturers to aim for products without latex. Elastic, thread, materials and packaging can be chosen that avoid latex use. Most items procured for use within a hospital environment are not made with latex. Latex allergy causes problems for patients and for health workers (HSE, 2018). The FDA (2014) recommends avoiding the term “latex-free” as it is difficult to ensure this. The FDA recommends the use of the statement “Not made with natural rubber latex”. If this statement is made without any qualification, it would apply to the medical product, its container, and any packaging. This is not compulsory, since health workers’ clothing, specifically bras, socks and underpants, are not required to be made without natural rubber latex.

# Information on MHRA website about what the application involves:

A manufactured theatre cap may count as a Class I medical device. People or companies who manufacture a Class I medical device need to fulfil some obligations:

1. Register as a manufacturer of Class I medical devices with the Medical and Healthcare products Regulatory Agency [www.mhra.gov.uk](http://www.mhra.gov.uk)
2. Pay (currently) £100
3. Submit a declaration about the medical device
	1. About the device in general (see suggestion below)
	2. About your particular theatre hat(s): Design and manufacturing process and quality control procedures. **Please ensure it has no latex components and state this.**
4. Put a CE mark on every device
5. Keep records

There is a lot more information on their website. I have tried to make it easier, by making the following pages “cut and paste” into your declaration. A number of surgeons, anaesthetists and theatre staff are very committed to this. The Medical Devices agency is keen to work with us to make it better.

The medical device directives apply to any thing that has a medical purpose and isn’t a medicine. The purpose of a thing is defined by the manufacturer of the thing and is dependent on what they say about it (the intended use statement).

### More information is on:

<https://www.gov.uk/government/collections/guidance-on-class-1-medical-devices>

Register here: <https://www.gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices>

If you are already registered with us and have a question about your registration details contact us on 020 3080 7272 or email device.registrations@mhra.gov.uk quoting your reference number.

## State that it will not be used sterile (which has additional requirements).

# CE marking

Information at: <https://www.gov.uk/government/collections/guidance-on-class-1-medical-devices>

The CE conformity marking consists of the initials ‘CE’ taking the following form:



— If the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

— The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

# Intended Use Statement:

* The Theatre hat is personal protective equipment (which also has to comply with the Health and Safety at Work Act)
* The hat is also to protect patients: part of the intended function is to protect patients from the staff members’ heads.
* For some hats, another function is to protect the patient from errors, that is by having the name on the front the intention is to protect the patient from the risk of hierarchy and misidentification et

If the manufacturer provides these as the intended use of the theatre hats, they need to be registered with the MHRA.

If the manufacturer is only claiming friendly or similar intentions with no medical use, they do not need to be registered with the MHRA. The organisation or an individual purchasing the hat is also free to buy these and use them for medical purposes, which means that they accept the risks

# Suggested wording to be used on the purchaser information sheet:

* Thank you for purchasing a Theatre Cap. There is evidence that this improves team cohesion and improves patient experience. There is also evidence that infection control is slightly improved with use of these cloth hats compared with traditional disposable hats.
* Please note:
	+ We advise purchasers to purchase at least three hats, to allow for laundry rotation
	+ If you are having your name on the hat, we advise that you also have your role stated to help other staff. Your name may be first name or surname or both.
	+ The Theatre Cap is covered by a standard NHS Dress Code or Uniform policy
	+ A new hat should be worn each day or each shift. It should be changed more often if contaminated
	+ Dirty Theatre Caps should be transported separately from clean Theatre Caps
	+ The Theatre Caps should be washed at 60 degrees or at 40 degrees and tumble-dried or dried on a washing line in sunlight and ironed.
	+ We advise that the theatre cap is not worn out of work.
	+ We advise that NHS staff should not be seen smoking in uniform.
	+ Some hospitals use colour-coded Theatre Caps to signify role, but there is no standardisation of this. You may wish to check and follow any local guidance.
* Because this item is only used in the course of your work, you may be entitled to claim the cost against income tax. We advise that you keep your receipt.
* Please notify us if:
	+ There is any shrinkage
	+ The letters become less legible
	+ There are any other problems with your theatre hat
* Our contact details are: …

# Information to help with MHRA application:

# A description of the clinical problem

In operating theatres, delivery suites and similar settings, there is a requirement for staff to cover their heads and keep any hair covered. This applies even to those who have no hair. This is part of the ordinary uniform for staff. This part of the uniform does not come into contact with patients. There is a requirement that the hat is clean. The most common arrangement in Higher income countries is to have disposable hats, thrown away at the end of a shift. This is in contrast to the rest of the uniform in theatres, which usually consists of “scrubs” – a top and trousers made of cloth. The scrubs are commonly laundered by the hospital and changed at the end of a shift or when visibly soiled. For completeness, the other common item of uniform is theatre shoes. Usually, each surgeon, anaesthetist or other staff member has their own theatre shoes (trainers or clogs) kept in a rack or locker and cleaned on occasion.

Some theatre staff scrub their hands and don a gown and gloves to perform the operation or work in the sterile area. Any name badge or lanyard cannot be seen.

Operating theatres are used intensively, and personnel often change, for example to allow staff to take breaks, to cover leave, or to allow operations to occur across 168 hours per week.

It is difficult to remember staff names and role, especially if they have scrubbed and have a gown on.

Teams work better if team-members know each other’s name and role. This helps with expectations and emergencies.

There are several issues:

* Theatre staff may not know or remember each other’s name
* Theatre staff may mistake what role another staff member is doing. Many make assumptions about what another’s role is. This is unconscious bias. This may mean a surgeon is mistaken for a nurse, for example.
* Despite a clear uniform policy from NHS employers, staff who choose to wear head-coverings, such as a hijab, as part of their religion often feel excluded. There is no clear way of dealing with their head covering. Many female Muslim medical students report not being permitted to scrub in for an operation whilst someone works out whether their head-covering can be covered with a disposable hat, or several hats. This is demeaning for these students. There is a clear NHS Employers policy on uniform and religion (NHS Employers, 2018).
* Theatre staff may feel literally “nameless and faceless” despite working in the operating theatres for a number of years. They can feel they lose their identity. The identical uniform and disposable hat may reinforce their factory-worker feeling, which contrasts with the passion and individuality they feel for their role. They may feel burnt out or despondent having to explain their role to every new member of staff, or have their name forgotten if they have not worked with someone for a number of weeks.
* Patients within the theatre environment do not know who is who. They may have met the surgeon and anaesthetist on the ward, but might not recognise them when the staff are all in identical uniforms and the patient has been deprived of hearing aids, contact lenses and/or spectacles.
* The disposable hats go to landfill, creating more waste.
* Ensuring a supply of disposable hats currently incurs issues with supply, delivery, transportation, ordering and cost for each hospital. The NHS has a large environmental impact and measures to improve sustainability should be considered (Sustainable Development Unit, 2014).

# The device

* Theatre hats have been manufactured out of cloth, in individual colours or patterns. These make staff feel more self-respect. The staff have several and launder them themselves.
* Many of these theatre caps can have a name and role added. This allows other members of the team to identify them and request tasks.

# Literature review

There is a body of literature covering different aspects:

### Around theatre staff forgetting names and teams working better when names are visible on hats and individual staff members are identifiable.

There is increasing evidence that teams work better if people know that having a name and role displayed on their theatre cap is effective, as the #TheatreCapChallenge (Hackett, 2018). Other literature has focussed on the teams working better if people know each other’s name and role (Leonard et al, 2014, Bobb et al, 2017). Patient safety may be improved if there is no doubt about name and role, especially with changes of personnel during an operation or in an emergency. Some studies show theatre staff forget 30-50% of names even after briefing (Birnbach et al, 2017; Burton et al, 2018). Having clarity about the expectations for each student or staff member increases respect and reduces bullying (RACS, 2016).

### Around unconscious bias

There is evidence that people are treated differently if others do not realise their role (RCSEng, 2016). Medical students in particular often feel ignored in surgery (Sutton, 2014). If medical students have a surgical placement with low interactivity, they feel negative towards the specialty in the future (Sutton et al, 2014).

### Around infection control

There is good evidence that cloth hats do not increase the risk of infection to patients, providing that they are washed daily. Cloth hats were found to be superior to disposable hats in terms of infection risk when tested in simulated operating theatre environments (Markel et al, 2017a; Markel et al, 2017b). In America, several research reports noted to a change to disposable bouffant hats resulted in increased Surgical Site Infections compared with the previous theatre hats that were cloth hats or disposable skull caps (Shallwani et al, 2018; Farach et al, 2018; Haskins et al, 2017).

### Around landfill

There is some evidence that viscose used to manufacture paper hats is a risk to the environment when it degrades. There is a strategy to improve the sustainability of procurement (Sustainable Development Uni, 2014).

## Organisations that have approved the use of cloth hats

Other organisations have approved the use of cloth hats, including the American College of Surgeons (ACS, 2016) and the Association for Peri-operative Practice (AFPP, 2018). There is precedent for treating this under an NHS Dress code or Uniform policy (NHS Employers, 2018).

## Practicalities

Where cloth theatre hats are in use, practicalities need to be considered. A clear policy is best; this should include:

* Each staff member is advised to purchase at least three hats, to allow for laundry rotation
* The name may be first name or surname or both. The role should be stated.
* The Theatre Cap is covered by a standard NHS Dress Code or Uniform policy, for example:
	+ A new hat should be worn daily, or changed more often if contaminated
	+ Dirty Theatre Caps should be transported separately from clean Theatre Caps
	+ The Theatre Caps should be washed at 60o Centigrade or at 40o Centigrade and tumble-dried or dried on a washing line in sunlight and ironed.
	+ Staff should not wear the item out of work.
	+ Staff should not be seen smoking in uniform.
	+ Some hospitals use colour-coded Theatre Caps to signify role, but there is no standardisation of this. Local guidance may be useful.
* It is better if the Theatre hat contains no natural latex (FDA, 2014; HSE, 2018)

Where cloth hats are in use, funding may be an issue (with a cost for each cap purchased). Some NHS Trusts (eg Portsmouth) have arranged bulk orders using charitable funds.

# List of risks and mitigations

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| 1 | Risk that surgeons, anaesthetists and theatre staff will not wash their theatre hats and there will be an infection risk | Labels will clearly state the need to wash the hats. Information will advise purchasing sufficient hats to have a laundry strategy |
| 2 | Risk that surgeons, anaesthetists and theatre staff will not store their theatre hats appropriately | Labels will clearly state the need to store and transport clean and dirty hats separately. |
| 3 | Risk that people will consider surgery frivolous if the surgeon, anaesthetist or theatre staff member has a humorous theatre hat. | The range of fabrics, patterns and colours will be kept under review. Any comments about poor taste will be acted upon. It is hoped that the need to treat every staff member as an individual will far outweigh any distress that a humorous hat might convey to a patient or relative. |

# Summary of literature review:

There is evidence showing that named cloth Theatre hats for staff are highly effective in improving communication and patient safety and that large studies confirm infection risks are reduced compared with paper hats.

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# A risk benefit analysis

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| --- | --- | --- |
|  | Risk | Benefit |
| 1 | Infection risk | It is likely that a cloth hat will have better infection control properties than a disposable hat, from the literature review. Furthermore, surgeons and other theatre staff who are less stressed produce less sweat, so the gains in calmness  |
| 2 | Risk of being considered frivolous or silly | It appears that the benefit of team-members knowing each others’ name and role, particularly when under stress, far outweighs any element of frivolity. |
| 3 | Risk of staff feeling demoralised by having to do additional washing | We hope this is outweighed by every staff member feeling valued as an individual and having an identity and respect. |
| 4. | Risk that staff feel pressured to spend money on three cloth hats when these will be only be used at work as part of a uniform. | We hope that organisations will see the benefit of team-working and offer to purchase theatre hats for new staff.We rely on theatre staff purchasing their own hats where necessary.We hope that our statement that the theatre hat is a medical device may mean that its purchase can be off-set against pre-tax income.It should be noted that some NHS Trusts have been able to use charitable funds for this purpose. |

# A description of any ongoing monitoring that is needed

Each theatre cap will be issued with instructions for the purchaser to contact the manufacturer:

* If shrinkage occurs
* If the writing becomes less legible over time

# Conclusion of evidence and risk: benefit analysis

Named cloth theatre hats for staff have been used in a number of countries and are well liked by staff. They improve communication and patient safety and that large studies confirm infection risks are reduced compared with paper hats. Some practicalities are required for so that users have clarity, for example labelling about laundry requirements and leaflets.

# Technical information below. Any detail that the MHRA needs should be supplied by the manufacturer:

Technical documentation

You must keep technical documentation that demonstrates that your products conform to the requirements of the [MDD](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011) . You must have this documentation prepared before drawing up the EC declaration of conformity. You must keep the documentation for a period ending at least 5 years after the last products have been manufactured. MHRA can ask to see the documentation at any time.

The technical documentation must cover all of the aspects listed below.

**Description**

A general description of the product, including any variants (for example names, model numbers and sizes).

**Raw material and component documentation**

Specifications such as: details of raw materials; drawings of components and/or master patterns; quality control procedures.

**Intermediate product and sub-assembly documentation**

Specifications including: appropriate drawings and/or master patterns; circuits; formulation specification; relevant manufacturing methods; quality control procedures.

**Final product documentation**

Specifications including: appropriate drawings and/or master patterns; circuits; formulation specification; relevant manufacturing methods; quality control procedures.

**Packaging and labelling documentation**

Packaging specifications and copies of all labels and any instructions for use.

**Design verification**

The results of qualifications tests and design calculations relevant to the intended use of the product, including connections to other devices in order for it to operate as intended.

**Risk analysis**

Looks at whether risks associated with the use of the product are compatible with high-level protection of health and safety and are acceptable when weighed against the benefits to the patient or user. For example, if biocompatibility is relevant (i.e. for invasive devices) you will need to compile and review existing data or test reports based on the relevant standards.

**Compliance with essential requirements**

You need to demonstrate that you meet the relevant essential requirements outlined in annex 1 of the [MDD](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011). Not all of the essential requirements will apply to your product so you will need to identify which requirements do apply and provide evidence to demonstrate how you meet these. One way of demonstrating that you meet specific essential requirements is by developing your product in accordance with relevant [harmonised standards](https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en). The technical documentation needs to include a description of how each relevant essential requirement has been complied with including a list of relevant harmonised standards that have been applied, in full or in part, concerning the manufacture and design of the product.

**Clinical evaluation in accordance with Annex X**

A clinical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device. The data needs to adequately demonstrate that the product fulfills its intended purpose. The intended purpose includes any claims made as part of marketing material supplementary to those made in the technical file.

**EC declaration of conformity**

In order to put the CE marking on your products, you must follow the EC declaration of conformity procedure described in Annex VII of the MDD. You must do this before placing the device on the market.

You must keep the documentation for a period ending at least 5 years after the last products have been manufactured. This is so that MHRA can investigate any problems with a device even if it is no longer on the market.

**Clinical evaluation**

You must carry out a clinical evaluation for all class I devices to demonstrate conformity with the essential requirements of the [MDD](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011). The evaluation involves looking at published clinical data to prove that the medical device works as intended and is safe to use.

The European Commission’s guidance [MEDDEV2.7/1](http://ec.europa.eu/DocsRoom/documents/17522/attachments/1/translations/) describes what is expected in an evaluation.

Note: a clinical evaluation is not the same as a clinical investigation (CI). A CI may form part of a clinical evaluation. For example, if there isn’t enough pre-existing evidence to demonstrate that the device conforms with the essential requirements of the MDD, a specifically designed CI may be necessary. In this case you will have to [notify MHRA in advance](https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device) of doing the investigation. The European Commission’s document [MEDDEV 2.7/4](https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device) includes guidance on deciding whether you need to do a CI.

The clinical evaluation of the device needs to be continually reviewed after the device has been placed on the market. Your review should take into account the outcomes of any post market surveillance activities or user feedback. The technical documentation should be updated accordingly.