Purchasing medical devices for social care
9th July 2020
Jenifer Hannon
Aims

• Which items should providers buy
• How/why decision to expedite CE marking was made
• How providers can find out if a non-CE marked product is suitable

• I am going to focus on “protective medical devices” which fall under the remit of the MHRA and must meet the requirements of the Medical Device Regulations
The regulations and the responsibilities of manufacturers and importers
The Regulations

If intended to be worn (or held) to protect the wearer: EU Regulation 2016/425 on Personal Protective Equipment (PPE). The market surveillance authority for PPE is HSE.

If intended to protect the patient [and medical staff]: Medical Devices Regulations (MDR 2002) which implements Medical Device (MD) Directive 93/42/EEC. Or MDR 2017 (delayed).

If dual purpose (MD and PPE), the product must comply with MDR. In addition, they must meet the relevant essential health and safety requirements (EHSR) of the PPE Directive.

MHRA is the market surveillance authority for Medical Devices.
The Role of MHRA

MHRA is the market surveillance authority in the UK for Medical Devices. Key functions (not exclusive):

• Manage the adverse incident reporting system
• Work with manufacturers to act upon and resolve safety issues with medical devices
• Issue safety notifications and guidance to the health system and the public
• Designate and audit the Notified Bodies based in the UK who assess medical devices against the requirements of the MDR
• Grant “derogations” (exceptional use authorisations)

We only consider applications where there is a clear clinical need and there is no available supply of CE marked or already derogated alternatives

Medical devices granted an exceptional use authorisation can be sold to the NHS and within the social care setting to ensure a continued supply of medical devices
• Has ultimate responsibility for compliance including processes carried out by other parties
• Must hold documentation demonstrating compliance
• Appoint a Notified Body where appropriate (e.g. sterile products and surgical gloves which apply to this document).
• Affix CE Mark
• Mark product with its name and address
• Mark product with the EU Representative if legal manufacturer is outside of EU
• Draw up Declaration of Conformity
Medical Device Process – Class I devices only including Class I sterile (surgical face masks, examination gloves, surgical gowns)

- Manufacturer creates technical documentation and verifies compliance with essential requirements and issues declaration of conformity.
- Location of manufacturer:
  - EU: Register Devices with CE, where manufacturer/AR based.
  - Non-EU: Appoint Authorized Representative, contract between both parties required.
- Is the device sterile?
  - yes: Appoint a Notified Body for sterility aspects and obtain CE certificate.
  - no: All must be shown on the declaration of conformity and labelling.
Assure themselves that product is compliant with the Regulations by:

• Requesting and reviewing the declaration of conformity and any associated CE certificate from a Notified Body (a Notified Body is **not** required for Class I non-sterile products like a non-sterile surgical face mask or examination glove).

• Verifying that the device has been registered in an EU Member State

• Verifying that the device and any associated instructions for use carry the CE mark (and Notified Body Number if applicable).

• Verifying that the name and address of the manufacturer and that of the Authorised Representative (if applicable) are on the device and any packaging / labelling and instructions for use.

**The importer/distributers details may be listed, however the manufacturer’s details must not be removed and should be clearly visible.**
Medical devices
Medical Device - Surgical Face Masks – single use – sterile or non sterile

• These types of mask look similar either with ear loops or with ties
• The packaging should state the type (II or Type IIR only if to BS EN 14683), or appropriate description of mask
• CE mark on box/label (not on individual devices). No Notified Body number needed here unless sterile
Medical Device - Surgical Gowns
non sterile or sterile – single use or reusable

- Some gowns are intended to be reused and will come with instructions on how to reprocess them
- User will select the gown based on its performance and its anticipated challenges when in use (duration of use/exposure to volumes of liquid etc)
- CE mark on box/label or individual packaging. No Notified Body number needed here unless sterile
Medical Device - Surgical and Examination Gloves

- Single use surgical (sterile) gloves
- Single use examination (usually non-sterile) gloves
- CE mark on box/label or individual packaging.
- No Notified Body number needed here unless sterile or a surgical glove
Normal requirements for CE marked Protective Medical Devices C-19


- **Class I non-sterile**: masks, examination gloves and surgical gowns **do not** require the intervention of a Notified Body.

- **Class I sterile masks and sterile surgical gowns, and Class IIa sterile surgical gloves will require** intervention of a Notified Body (NB). A NB number will be next to the CE mark.

- The information in this document relates **specifically** to these types of medical devices and not medical devices that fall into other classifications.

- In all cases there must be a Declaration of Conformity drawn up by the legal manufacturer before applying the CE mark

- A quality management system is not mandatory for Class I. Other rules apply see above link about Technical Documentation
What to look for when deciding to purchase
Q: What regulation is being declared on the Declaration of Conformity

It shall be: **93/42/EEC Medical Device Directive** or **Medical Device Regulation 2017/745** (came into force 2017 but delayed the full implementation for one year - 26 May 2021)

Q: What standards are being declared compliance with. Do they have a test report and you can check via a range of on-line certificate sites if valid (see slide 33 for range of websites)

Q: The Notified Body Number is it real? Is the NB approved for MD? This can be checked here: [https://ec.europa.eu/growth/tools-databases/nando/](https://ec.europa.eu/growth/tools-databases/nando/). This will only apply for sterile medical devices or surgical gloves and the Notified Number shall be next to the CE mark

Q: Will the Manufacturer supply you a copy of the Declaration of Conformity? It is a legal requirement for the Importer, manufacturer and EU Representative to have one.

##This is not a ‘EC/CE certificate’ which is issued by a Notified Body (certified for sterility aspects, production or full quality assurance for example).###

Q: Have you got a picture, what is on the label of the MD – is it in English – can you tell what the device is by the label, are there instructions for use (where appropriate)?
Non CE marked Medical Devices

- Before you purchase and ideally before stock enters the UK, you must establish if the manufacturer / supplier has been given a derogation approval by MHRA to supply to the UK.

- A spreadsheet of derogated protective medical devices are circulated regularly by MHRA to key stakeholders including CAPA, DMC and Devolved Administrations.

- Check the list first. This is published on gov.uk site:
  

- If not on the list, an application to MHRA must be sent to MHRA by the manufacturer/supplier via the system described below:

  https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe

  This contains Essential Technical Specifications and User Guide on how the manufacturer/supplier can apply for derogation to MHRA. (It is under revision). They can also apply direct:

  Devices.ExceptionalUse@mhra.gov.uk
Non compliant – fake/invalid?

Case 1: Manufacturer submitted ICT report to BS EN 14683 Type IIR mask standard including splash resistance results

Outcome: Certificate does not exist
Non compliant – fake/invalid?

Case: This registration certificate to Quality Management System is invalid

Outcome: No Hong Kong office - Fake
Case 3: Nelson laboratories report for surgical face claiming compliance with BS EN 14683 Type II mask

Scan of report rather than certified PDF – Text out of line

Outcome: Nelson contacted and confirmed fake
Standards
e.g., BS EN, ISO or Other

and Labelling

Note, it is not mandatory to use harmonised, European or other standards to meet the requirements of the relevant Regulations

(Date of standard(s) can be previous version)
Useful Websites (China, Rapid Alert System for dangerous non-food products, Medical Devices/PPE Minimum Specification)

- https://qualityinspection.org/testing-laboratories-china/
- https://www.cnas.org.cn/english/
- https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search&lng=en#searchResults
Medical Device: Surgical Mask Standards (not mandatory)

- May comply with BS EN 14683:2019 Medical face masks – Type II or Type IIR – for this mask you are looking for the test method results under Monograph 5.2.4 – “Splash resistance”

- Or ASTM F2100 Level 2, or 3, or equivalent technical solution

- There are also Chinese standards too (quite a few!). Mapping document across standards is being prepared by MHRA to circulate shortly

- Comparison of ASTM and BS EN 14683:2019:

### MEDICAL FACE MASK TESTS AND REQUIREMENTS

<table>
<thead>
<tr>
<th>ASTM F2100-19</th>
<th>EN 14683:2019 Barrier Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Level 2</td>
</tr>
<tr>
<td>295</td>
<td>≥98</td>
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</table>

- **Physical Testing**
  - Synthetic Blood ASTM F1862, ISO 20639
    - Pass at 80 mmHg
    - Pass at 120 mmHg
    - Pass at 180 mmHg
    - Not required
    - Pass at ≥ 36.0 kPa (120 mmHg)

- **Safety Testing**
  - Not required

- **Biocompatibility**
  - ISO 10993
  - Complete an evaluation according to ISO 10993

- **Sampling**
  - ANSI/ASTM F2100-14, ISO 2857-1
  - Minimum of 5 masks up to an ACL of 4% for BFE, Delta P and Microbial Cleanliness
  - 32 masks for Synthetic Blood (Pass = ≤29 passing, Fail = ≤28 passing)
  - 14 masks for flammability
Medical Device: Surgical Masks packaging/labelling

- Labelling should indicate the type of mask (eg. Type I, II or IIR if BS EN 14683, or of similar wording like fluid resistance).
- Manufacturing and/or Expiry date.
Surgical Gown standards (not mandatory)

- Usually comply to BS EN 13795-1:2019 Surgical clothing and drapes - Requirements methods. Standard or High Performance
- AAMI PB70 Level 1-4 or equivalent technical solutions. Mapping document across standards is being prepared by MHRA to circulate shortly
- Example of testing requirements under BS EN 13795-1:2019: (critical area are joints on the gown like seams in sleeves

Table 1 — Characteristics to be evaluated and performance requirements for surgical gowns

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Test method (for normative reference see Clause 2)</th>
<th>Unit</th>
<th>Requirement</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Standard performance</td>
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<td></td>
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<td>Critical product area</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Critical product area</td>
</tr>
</tbody>
</table>
| Microbial penetration — Dry                 | EN ISO 22612                                        | CFU  | Not required | ≤ 300
|                                             |                                                    |      | Not required | ≤ 300
| Microbial penetration — Wet                 | EN ISO 22610                                        | I / g| ≥ 2.8 b  | Not required | 6.0 b c | Not required |
| Cleanliness microbial / Bioburden           | EN ISO 11737-1                                      | CFU/ | ≤ 300 | ≤ 300 | ≤ 300 | ≤ 300 |
|                                             |                                                    | 100 cm² | | | | |
| Particle release                            | EN ISO 9073-10                                      | log_{10} | ≤ 4.0 | ≤ 4.0 | ≤ 4.0 | ≤ 4.0 |
|                                             |                                                    | (list | | | | |
|                                             |                                                    | count) | | | | |
| Liquid penetration                          | EN ISO 811                                          | cm H₂O | ≥ 20 | ≥ 10 | ≥ 100 | ≥ 10 |
| Bursting strength — Dry                     | EN ISO 13938-1                                      | kPa  | ≥ 40 | ≥ 40 | ≥ 40 | ≥ 40 |

Charteristic | Test method (for normative reference see Clause 2) | Unit | Requirement |
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<td></td>
<td></td>
<td>Critical product area</td>
</tr>
<tr>
<td>Burning strength — Wet</td>
<td>EN ISO 13938-1</td>
<td>kPa</td>
<td>≥ 40</td>
</tr>
<tr>
<td>Tensile strength — Dry</td>
<td>EN 29073-3</td>
<td>N</td>
<td>≥ 20</td>
</tr>
<tr>
<td>Tensile strength — Wet</td>
<td>EN 29073-3</td>
<td>N</td>
<td>≥ 20</td>
</tr>
</tbody>
</table>
Surgical Gown packaging and labelling

• If applicable, must be labelled STERILE if appropriate along with the method of sterilisation. In this case there will be Notified Body Number next to CE mark

• Manufacturing and/or Expiry date

• Must include warnings on its use in certain areas (flammability) where appropriate

• If applicable, reprocessing instructions for reusable gowns (those intended by the manufacturer to be reprocessed)

• Usually compliant with BS EN 13795 or AAMI PB70 or equivalent technical solution

• Under BS EN 13795 there are two types based on the fluid performance in critical areas on the gown:
  - Standard performance (SP)
  - High performance (HP)

• Under AAMI there are 4 levels of fluid resistance. 4 being the highest. On the label it might have the level as droplets. Level 2 and above is needed

• Must state the type of gown – such as standard (SP) or high performance (HP) or equivalent wording as above
Surgical Gown Packaging

365 Healthcare

STANDARD PROTECTION SURGICAL GOWN

Contains:
1 x Sterile gown
2 x Hand towels
1 x SMS wrap

MHRA
Surgeons Gloves standards
(not mandatory)

- Option 1 (all materials) BS EN 455-1:2020. All requirements and testing for freedom from holes.
  AND BS EN 455-2:2015 All requirements and testing for physical properties.
  AND BS EN 455-3:2015 All relevant requirements and testing for biological evaluation (in terms of sensitivity for the wearer e.g. latex protein)
  AND BS EN 455-4:2009 * Requirements and testing for service life determination
  AND if BS EN 556-1:2001 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices

- OR Option 2: ASTM D3577-19* Standard specification for Rubber surgical gloves. All requirements.

- OR Option 3 - equivalent technical solutions to all the above (where applicable)

- Gloves made of well-established materials/formulation shall have an expiry date with a provisional date of <3 years (generally industry-wide accepted and well understood). BS EN 455-4 testing/studies may be undertaken. If not, justification shall be recorded in the technical documentation for the shelf life claim.

ASTM glove methods have an acceptable quality limit (AQL) higher than BS EN 455 which means more failures are allowed in ASTM compared to BS EN 455. This shall be considered during the review for derogation by MHRA for non-CE marked gloves
Examination Gloves standards (not mandatory)

- Option 1 (all materials) BS EN 455-1:2020. All requirements and testing for freedom from holes.
  
  • AND BS EN 455-2:2015 All requirements and testing for physical properties.
  
  • AND BS EN 455-3:2015 All relevant requirements and testing for biological evaluation (in terms of sensitivity for the wearer e.g. latex protein)
  
  • AND BS EN 455-4:2009* Requirements and testing for service life determination
  
  • AND if sterile: BS EN 556-1:2001 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
  
- OR Option 2 (based on material): All requirements relating to its material
  
  • ASTM* D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
  
  • ASTM* D3578-19 Standard Specification for Rubber Examination Gloves
  
  • ASTM* D5250-19 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application (not seamed gloves)
  
- OR Option 3 - equivalent technical solutions to the above where applicable
  
  • Gloves made of well-established materials/formulation should have an expiry date with a provisional date of <3 years (generally industry-wide accepted and well understood). BS EN 455-4 testing/studies may be undertaken. If not, justification shall be recorded in the technical documentation for the shelf life claim

* ASTM glove methods have an acceptable quality limit (AQL) higher than BS EN 455 which means more failures are allowed in ASTM compared to BS EN 455. This shall be considered during the review for derogation by MHRA for non-CE marked gloves
Surgical/Examination Gloves packaging labelling

• If applicable, must be labelled STERILE along with the method of sterilisation. In this case there will be Notified Body Number next to CE mark.

• Gloves containing latex must be labelled with the symbol for latex on at least the smallest packaging unit and caution placed in the instructions for use against its use where there is a known allergy to latex.

• Must have an expiry date

• Must specify the size

Sterile Surgical Gloves
In Summary
TOP TIPS from MHRA

➢ If CE marked on box – check its Declaration of Conformity (Doc)
➢ If no CE mark on box – has a derogation been given by MHRA
➢ Where appropriate check validity of certificates issued by test houses, Notified Bodies (e.g. TUV), check NB scope (list of on-line certification check in next slide).
➢ If you are suspicious about the DoC, CE certificate, test reports, or CE mark and need an opinion – email and provide evidence to:

Use the ‘NHS proforma’ for contacting regulatory authorities (see next slide)
➢ If no CE mark and derogation application to MHRA is required; purchasing teams (and manufacturers) shall follow guidance:

https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe

You should use the ‘NHS proforma’ for contacting regulatory authorities (see next slide)
Proforma and key MHRA email addresses

Regulatory advice:

Email - Devices.regulatory@mhra.gov.uk

Derogation applications:


Email - devices.exceptionaluse@mhra.gov.uk
Validity checks for medical devices

Nelson Laboratories – Check properties for ‘paperstream capture’ or email jhone@nelsonlabs.com


ECM: http://entecerma.it/certificate.php

SGS: https://www.sgs.co.uk/en-gb/certified-clients-and-products/certified-client-directory


ICR Polska: https://cert.icrpolska.com/


Pony Testing International Group: csx@ponytest.com

TUV Rheinland: https://www.dincertco.tuv.com/?locale=en


Questions