



English Ambulance Service:

- Heads of EPRR
- Managers of HART Services

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Dear Colleagues

RE: MIBS STRETCHER

At the last meeting of the National Operations Group, NARU took an action to look into an issue with the MIBS Stretcher currently being used by HART Units and provide a position statement back to the next meeting February. After looking into this matter, I feel it appropriate to issue this position statement now, rather than waiting until the next meeting.

The Issue

The MIBS Stretcher does not have a CE Marking. This issue applies to the following specified HART logistics and respective NARU Equipment Data Sheets (EDS):

- MIBS Stretcher [EDS 108]
- Spinal Inserts [EDS 146]
- MIBS Strop (for vertical lifts) [EDS 113]
- Bariatric MIBS [EDS 109]

The manufacturer may have been reliant on an exemption available in the EU Directive for supplying equipment to the Armed Forces and Police for self-defence or rescue operations. The manufacturer can provide a certificate of conformity and a NATO stock number.

MIBs stretchers have been used frequently by HART Units for the last seven years without any nationally reported incidents or risks arising from the equipment. MIBs stretchers are being subjected to six monthly LOLER (Lifting Operations and Lifting Equipment Regulations 1998) inspections to ensure they are in a safe and suitable state for lifting operations.

Legal / Regulatory Requirements

NARU includes minimum conformity requirements for all safety critical equipment (used for interoperable capabilities) in its Equipment Data Sheets (EDS). The EDSs for MIBS (and related items) currently require them to be CE Marked.

CE Marking is a mandatory requirement for certain products sold and used in the European Union (including the United Kingdom). The types of product include; personal protective equipment, medical devices, equipment and protective systems intended for use in potentially explosive atmospheres, machinery, etc. CE marking is not required for items such as; chemicals, pharmaceuticals, cosmetics, foodstuffs. CE Marking is also not a requirement for ladders, or tools providing they are not classed as machinery.

The main legal provisions are included in: Regulation (EC) No. 765/2008

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Rescue stretchers are not specifically stated as requiring a CE marking. Therefore, an assessment of relevant product categories is required to determine whether this is the case. Most lifting equipment is caught within the definition of machinery in the Machinery Directive due to the potential for wide interpretations (2006/42/EC). Where LOLER regulations apply to lifting equipment, which is safety critical in nature, CE Marking and Certificates of Conformity are usually mandatory requirements, particularly where the devices include mechanical parts. The MIBS are constructed from canvas / fabric and do not have any mechanical moving parts. It is therefore unclear to us whether CE Marking is appropriate for MIBS.

The NARU EDSs for MIBs (and related equipment) also require that they are subject to inspection and maintenance regimes that conform with the Lifting Operations and Lifting Equipment Regulations 1998 (LOLER) and the Provision & Use Working Equipment Regulations 1998 (PUWER).

Actions being taken by NARU:

- The manufactures and UK suppliers of the MIBS equipment have been contacted. They have provided certificates of conformity and a statement.
- The manufactures have been asked to scope the feasibility of obtaining CE conformity for the items in question, which they have agreed to do.
- A national risk assessment is being completed and will be included within the National Operations Group Risk Register.
- Guidance is being sought from the Health and Safety Executive on whether the current inspection regime for MIBS (6 monthly LOLER testing and conformity with the PUWER requirements) is sufficient to safely maintain the use of MIBS operationally without CE Marking.
- At this stage, NARU is of the view that the risk to staff and patients arising from the lack of CE Marking can be mitigated and controlled through the current maintenance regime of rigorous LOLER inspections and compliance with PUWER requirements.

Actions recommended for Trusts:

- Trusts should ensure that each MIBS and associated equipment is being subjected to LOLER inspections every 6 months in line with the respective EDS requirements.
- Trusts should conduct their own local risk assessment and decide whether MIBS should continue to be used operationally in the interim period.
- For this interim period, NARU is suspending the obligation to have MIBS available as part of the minimum equipment provisions for interoperable capabilities (i.e. MIBS will be an optional provision rather than a mandatory one for this interim period and until further notice).

Yours faithfully,



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