HEALTH AND SAFETY AUTHORITY

The European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 and 2013

Competent Authority Exemption 01/2014

Applicable To National Road Transport Only

The Carriage of uncleaned medical devices or equipment

In accordance with the provisions of ADR, the Health and Safety Authority, as competent authority appointed under Regulation 10 of the European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 and 2013, and in accordance with Regulation 5 (4) (a) of the said regulations, hereby exempts the relevant participant from ADR 2.2.62.1.5.7, in so far as where ADR requires the use of packaging tested in combination to be capable of retaining the medical devices and equipment when dropped from a height of 1.2 m, a packaging method deemed to provide an equivalent level of protection may be used. The transport operation shall, however, comply with the provisions contained in this document.

Purpose

To allow the relevant consignor/packer to ensure that medical devices or equipment potentially contaminated with or containing infectious substances which are being carried for disinfection, cleaning, sterilisation, repair or equipment evaluation are packed in packaging designed and constructed in such a way that, under normal conditions of carriage, cannot break, be punctured or leak their contents, in the absence of documentation to verify that the packagings in combination are capable of retaining the medical devices and equipment when dropped from a height of 1.2m (according to the provisions of ADR 2.2.62.1.5.7).

The following supplementary provisions shall be complied with:

1. The medical devices and equipment potentially contaminated with or containing infectious substances to be carried under the exemption specifically exclude the dangerous substances listed in ADR 2.2.62.1.5.7 (a), (b) and (c), i.e. medical waste (UN3291), medical devices or equipment contaminated with or containing infectious substances in Category A (UN No. 2814 or 2900), or dangerous goods that meet the definition of another class.

2. The medical devices and equipment are packaged according to the packaging method as follows:
    a. The soiled item shall be placed in a mesh basket.
    b. The mesh basket shall be placed in a bag certified to be leak proof at a pressure differential of at least 75KPa (inner packaging).
    c. An absorbent pad shall be placed underneath the mesh.
    d. The inner packaging shall be sealed in line with the manufacturer's instructions, which shall be printed on the bags and are as follows:
        i. Expel excess air from the bag
        ii. Peel off tape to expose the adhesive
        iii. Apply pressure to closure working outwards to the edges pressing firmly to avoid any gaps in the seal.
    e. The inner packaging shall be placed in secondary packaging (plastic bag), which shall be tied and secured with swan neck style with cable tie.
    f. The double bagged tray shall be placed on the shelf of a UN approved outer packaging marked with '50B/Y' (e.g. CSSD trolley or equivalent).
    g. The exterior of the outer packaging is marked "USED MEDICAL DEVICE" or "USED MEDICAL EQUIPMENT".
    h. The outer packaging shall be locked and secured in the carrier vehcile using ratchet and anchor straps.

3. An enzyme spray may be used to coat the uncleaned medical devices or equipment as a pre-packaging option, to increase cleaning efficiency.

4. The uncleaned medical devices and equipment shall not include broken glass, needles, or sharp objects capable of puncturing, cutting or penetrating the packaging material.

5. Packages must be secured in the outer packaging to prevent movement during carriage by filling voids with dunnage. This may be achieved by ensuring that each shelf is filled with trays, or by filling any empty space with empty trays or other appropriate packaging.

6. The outer packaging shall be designed to be maintained in an upright position. A vehicle tail lift shall be used to load and unload the packaging to and from the vehicle.

7. A copy of this exemption must accompany the transport documentation and shall be made available to anyone having a legitimate interest in the shipment.

8. This document shall not be used as documentary proof of correct classification. Classification remains the responsibility of the consignor.

9. Any incident resulting in loss of containment of a substance during the transport journey shall be reported immediately in writing to this Authority.

10. The Authority may withdraw this exemption for failure to observe any of these conditions, or for any other reason which the Authority deems sufficient.

11. Any application for renewal of this exemption must be accompanied by a list of any incidents involving the substance(s) that may have occurred. A nil return is required.

12. The carrier must consult with the National Roads Authority prior to carrying goods through a tunnel subject to the provisions of ADR.

13. In all other respects the relevant requirements of ADR shall be complied with.

14. This exemption is valid until the date of expiry, provided no changes are made to the ADR which would affect this approval in the intervening period.

This exemption is effective immediately and expires on **30th June 2017.**

M. O'Halloran

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