



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

Competent Authority Exemption 03/2016

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 to 2015, and in accordance with Regulation 5 (4) (a) of the said regulations, hereby exempts the relevant participant from ADR 2.2.62.1.5.9, 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 reusable invasive medical devices (RIMDs) 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, otherwise in accordance with the provisions of ADR 2.2.62.1.5.9.

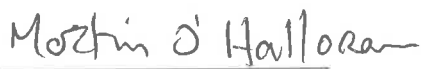
The following supplementary provisions shall be complied with:

1. The reusable invasive medical devices (RIMDs) potentially contaminated with or containing infectious substances to be carried under the exemption specifically exclude the dangerous substances listed in ADR 2.2.62.1.5.9 (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. An enzyme spray may be used to coat the uncleaned RIMDs as a pre-packaging option, to increase cleaning efficiency.
3. The RIMDs potentially contaminated or containing infectious substances of Category B shall not include tubing or free liquids, all of which shall be removed prior to packaging of the RIMDs.
4. The RIMDs are packaged according to the following packaging method:
 - a. The RIMDs shall be placed on a mesh basket/tray with an absorbent pad underneath the mesh.
 - b. The mesh basket/tray with absorbent pad shall be placed in a bag certified to be leak proof at a pressure differential of at least 75KPa (inner packaging).
 - c. 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.
 - d. The inner packaging shall be placed in secondary packaging (plastic bag), which shall be tied and secured with swan neck style with cable tie.
 - e. The double bagged trays shall be placed in rigid outer packagings that are designed and constructed in such a way that, under normal conditions of carriage, they cannot break, be punctured or leak their contents. The outer packagings shall meet the construction requirements of ADR 6.1.4 (where possible, UN approved rigid outer packaging will be used).
 - f. The inner and intermediate packagings shall be secured in the outer packaging to prevent movement during carriage by filling voids with dunnage.
 - g. The outer packaging shall meet the general packing requirements of ADR 4.1.1.1 and 4.1.1.2 and shall be designed to be maintained in an upright position.
 - h. The outer packaging shall be fully closed, locked, and shall be marked with orientation arrows in accordance with ADR 5.2.1.9.
 - i. The exterior of the outer packaging is marked "USED MEDICAL DEVICE" or "USED MEDICAL EQUIPMENT".
 - j. A written risk assessment shall be carried out on the transport of the packages to and from the vehicle for carriage, and the loading and unloading of the packages. The packages shall be transported using a method that will minimise the risk of damage to the packaging and its contents. Where appropriate, a vehicle tail lift shall be used to load and unload the packaging to and from the vehicle.
 - k. The outer packaging shall be locked and secured in the carrier vehicle using ratchet and anchor straps.
5. The uncleaned medical devices and equipment shall not include broken glass, needles, or sharp objects capable of puncturing, cutting or penetrating the packaging material.
6. A copy of this exemption must accompany the transport documentation and shall be made available to anyone having a legitimate interest in the shipment.
7. This document shall not be used as documentary proof of correct classification. Classification remains the responsibility of the consignor.

8. Any incident resulting in loss of containment of a substance during the transport journey shall be reported immediately in writing to this Authority.
9. The Authority may withdraw this exemption for failure to observe any of these conditions, or for any other reason which the Authority deems sufficient.
10. 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.
11. The carrier must consult with the National Roads Authority prior to carrying goods through a tunnel subject to the provisions of ADR.
12. In all other respects the relevant requirements of ADR shall be complied with.
13. 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 2018**.



Martin O'Halloran
CEO
Health and Safety Authority

