
	<h1 style="margin: 0;">SAFETY ALERT</h1>				
Ref: SA:013:00	RE: Revised Compliance Requirements for Transport of Uncleaned Reusable Invasive Medical Devices (RIMD) by Road - Expiration of Competent Authority Exemption 03/2016 The Carriage of Uncleaned Medical Devices or Equipment				
Issue date:	June 2018	Revised Date:		Review date:	June 2021
Author(s):	QID Decontamination Safety Programme in consultation with the National Health and Safety Function				
<h2 style="margin: 0;">S</h2>	<p>SITUATION:</p> <p>The Health and Safety Authority (HSA) provided an Exemption on 03/2016 that allowed the carriage of uncleaned Reusable Invasive Medical Devices (RIMD) by road, in packaging that was not tested to meet the criteria of withstanding the required 1.2 m drop test. The exemption applied to both transport boxes and transport trollies.</p> <p>The HSA exemption expires on the 30th June 2018 and will not be renewed.</p>				
<h2 style="margin: 0;">B</h2>	<p>BACKGROUND:</p> <p>The QID Decontamination Safety Programme in collaboration with the National Health and Safety Function provided guidance to the Services on what steps they needed to take to ensure compliance with the HSA exemption (Ref: <i>"Guidance on the Implementation of the Health and Safety Authority Competent Authority - Exemption 03/2016 on the Carriage of Uncleaned Reusable Invasive Medical Devices by Road (Ref QPSD-GL-021-1)"</i>).</p>				
<h2 style="margin: 0;">A</h2>	<p>ASSESSMENT:</p> <p>Compliant Transport Boxes</p> <p>Following a tender process, HSE Procurement have established a contract for the supply of transport boxes that fully meet the requirements for carriage of uncleaned RIMD under ADR road transport regulations. This consists of a reusable plastic box of dimensions 600 x 400 x 329mm with a maximum weight capacity of 20 kg.</p> <p>The transport boxes are supplied by O'Leary Medical on the HSE contract and come in two colours:</p> <ul style="list-style-type: none"> • Blue, part number BTB004A • Red, part number RTB004A. Refer to Contract Book & User Guide Ref: HSE 9499/17 for detailed information on the procurement process. 				

Each box must bear a label stating: “USED MEDICAL DEVICE” – a pocket is provided for holding such a label. The boxes are stackable and O’Leary Medical also supplies a dolly trolley on which the boxes may be placed for movement to and from vehicles – this is an optional extra that is not included in the supply contract (product code: BTB004TROL).



Existing Trolley Systems

It is recognised that some hospitals currently use a system consisting of plastic boxes with loose fitting lids (as illustrated below) carried inside an enclosed metal trolley. The lids of the plastic boxes are usually secured with cable ties as illustrated below.



Unless either the trolley or the boxes housed within the trolley have been shown to be capable of retaining medical devices when dropped from a height of 1.2 m, it will not be possible to continue using them for transporting uncleaned medical devices by road, past the expiry of the HSA exemption on the 30th June 2018.

It is not practical to have a complete existing trolley system subjected to a drop test. However, it is feasible to subject individual boxes to the drop test as follows:

- A box should be packed with clean RIMD in the same fashion as applied to contaminated RIMD.
- The lid should be secured with a minimum of two cable ties diagonally opposed.

	<ul style="list-style-type: none"> • The box should be dropped from a height of 1.2 m onto a hard floor, so that it impacts on one of the top corners (worst case). <p>The drop test is deemed successful if the box or lid do not crack or shatter, the cable ties do not break and the RIMD are not released or do not puncture the box or lid.</p> <p>The test should be documented, with photographic evidence retained for future audit. The location and procedure should be subject to a risk assessment process and any necessary precautions taken.</p> <p>If necessary you should seek the assistance of your local DGSA (DCM Compliance on: 061 405455) to advise on testing.</p> <p>If successful, then each box must be marked with: “USED MEDICAL DEVICE” as this represents the “package”. The outer trolley is deemed an “overpack” which should also be marked: “USED MEDICAL DEVICE”.</p>
R	<p>RECOMMENDATIONS:</p> <p>This Safety Alert withdraws the aforementioned HSE Guidance Document (Ref QPSD-GL-021-1) and outlines the steps that must be taken <u>with immediate effect</u> by Facilities who transport uncleaned RIMD by road under the current exemption.</p> <p>Note: Compliance with the requirements of the ADR will be an element of all future DGSA audits.</p>
Distribution:	CEOs Hospital Groups for onward dissemination to Hospital Managers and Decontamination Unit Managers.
Acknowledgments:	National Procurement Division, Quality Improvement Division, National Health and Safety Function and JJ Tobin, ChemHaz Solutions Ltd, HSEs National Dangerous Goods Advisor.