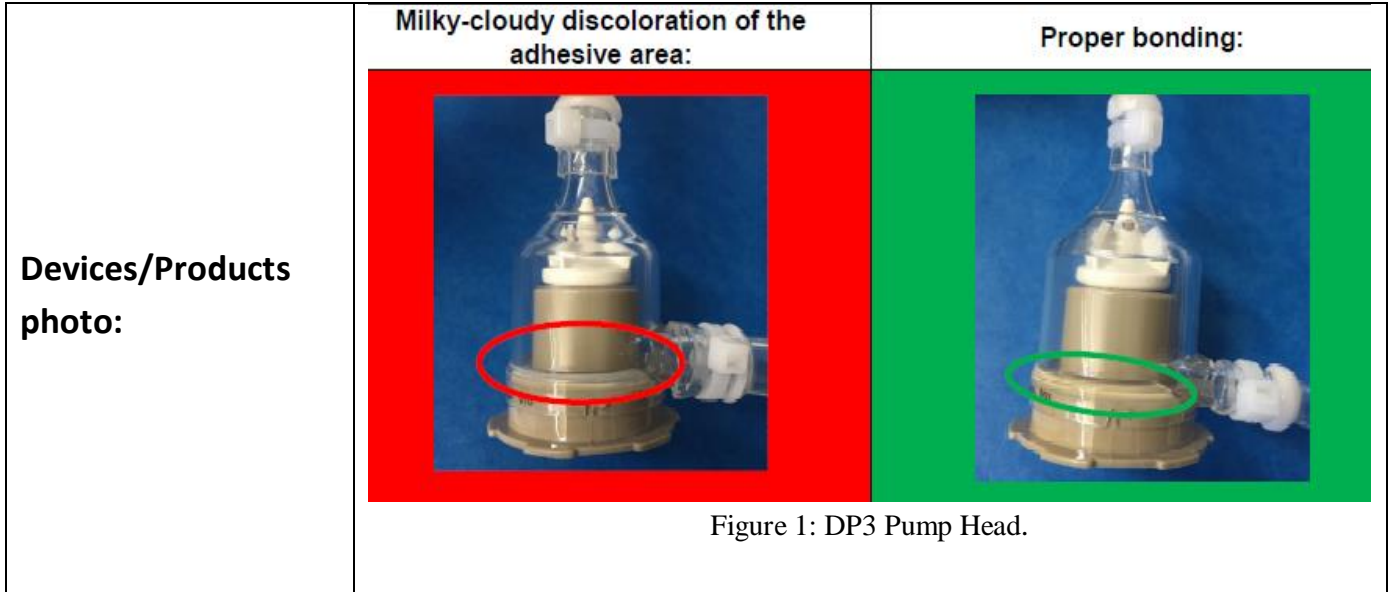


## Safety Communication

### iLA active Kits / iLA active iLA Kit - leak testing of the DP3 pump head

<b>Device/ Product Description:</b>	iLA active kits / iLA active iLA kit
<b>Brand Name:</b>	Xenios
<b>Lot numbers/Serials:</b>	All
<b>Manufacturer:</b>	Xenios AG
<b>Problem:</b>	<ul style="list-style-type: none"> <li>• This is a WARNING and Important additional control measures.</li> <li>• There is a procedure for <b>visual</b> and <b>leak</b> testing of the DP3 pump head MUST be performed prior to each use of the patient kit.</li> <li>• Non-observance of this procedure can lead to serious injury or even death of the patient!</li> </ul>
<b>Recommendation/ Actions:</b>	<ol style="list-style-type: none"> <li>1) Visual inspection of DP3 Pump Head: Please check the bonding of the DP3 pump head before using the patient kit. <ul style="list-style-type: none"> <li>➤ If the adhesive area of the housing connection is milky-cloudy, do NOT use the patient kit! (Figure 1)</li> </ul> </li> <li>2) Leak test DP3 Pump Head: For supplement to the Instructions for Use, section Preparation/Priming/De-airing please click (<a href="#">here</a>)</li> </ol>



You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should **report any adverse events** suspected to be associated with affected devices above (or other Medical Devices) to:

**[National Center for Medical Devices Reporting.](#)**

Medical Devices Sector  
Saudi Food and Drug Authority  
Postal Address: Saudi Arabia - Saudi Food and Drug Authority  
4904 northern ring branch rd - Hitteen Dist.  
RIYADH 13513 - 7148  
Tel: +966 (11) 2038222 Ext: 2995, 2952  
Fax: +966 (11) 2757245

Or

**[Saudi Vigilance](#)**

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Sincerely,  
NCMDR Team