

**To all customers and users of Dräger
latex test lungs and latex breathing
bags**

March 2014

Important Safety Notice!!!

Labelling of latex breathing bags

Products affected: Reusable latex breathing bags with part numbers 2165686, 2165953, 2165694, 2165708, 2165716, 2165724, 2165763, 2165775, 2165783, also as part of test lung with part number 8403201 and reusable anaesthesia sets with part numbers M33681, M27542, M34822, M34823 and M34824

According to our records, your hospital has been supplied with one or more of the affected products in the past two years

Dear Madam/Sir,

Within the framework of our worldwide product surveillance activities, we became aware of an incident where a user suffered an acute allergic reaction after using a Dräger latex test lung. The user did not suffer permanent injury. During our investigation of this incident we discovered that the breathing bag that belongs to the test lung and other latex breathing bags are labelled "NR". Although this is the standard abbreviation for natural rubber (latex), this labelling does not comply with the applicable international standards for medical devices. It is unclear whether the labelling of the product played any part in the reported incident.

Since our sales and order information regarding latex is quite clear and you intentionally ordered these products that have remained unchanged for many years, we assume that staff within your hospital are already aware that latex products are used.

We would nonetheless like to point out that the blue reusable breathing bags mentioned above which bear the marking "NR" do contain natural rubber (latex). Dräger breathing bags made of latex (blue) are clearly distinguishable from the latex-free version made of silicone (transparent) by their colour (see illustration on page 2). Latex products can cause allergic reactions. Please inform staff in your hospital accordingly.

Dräger Medical GmbH
Moislinger Allee 53-55
23558 Lübeck, Deutschland
Postanschrift:
23542 Lübeck, Deutschland
Tel. +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
UID-Nr. DE813745277

Bankverbindungen:
Commerzbank AG, Lübeck
Konto-Nr. 014 679 500
BLZ 230 400 22
IBAN DE95 2304 0022 0014 6795 00
SWIFT-Code COBADEFF230

Sparkasse zu Lübeck
Konto-Nr. 1 071 117
BLZ 230 501 01
IBAN DE15 2305 0101 0001 0711 17
SWIFT-Code NOLADE21SPL

Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 4358 HL

Vorsitzender des Aufsichtsrats:
Professor Dr. Nikolaus Schweickart

Geschäftsführer:
Stefan Dräger (Vorsitzender)
Dr. Herbert Fehrecke
Andreas Frahm
Gert-Hartwig Lescow
Anton Schrofner



Breathing bag made of natural rubber (latex)



Test lung with silicone breathing bag

Dräger is currently working on improved labelling on the products. Latex breathing bags with improved labelling should be available from May 2014. The test lung with part number 8403201 and the breathing bags in the reusable anaesthesia sets with part numbers M33681 and M27542 have been switched to the latex-free version made of silicone.

We would like to apologize for any inconvenience that this information may cause but believe it is essential in the interests of patient and user safety.

Please inform all relevant users in your hospital.

With many thanks in advance for your support.

With kind regards

Dräger Medical GmbH
Head of Key Application Field
Hospital Consumables & Accessories

