

<b>VBM Medizintechnik Quality Assurance</b>	<b>Summary list of VBM medical devices containing PVC that are subject to the labeling obligation according to Directive 93/42/EEC</b>	Date: 16.12.2011 Issue: 5 Page: 1 of 3
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Following list gives a survey on softener containing medical devices from VBM that require a labeling according to Directive 93/42/EEC.

In the moment some VBM-products contain the softeners DEHP (Diethylhexyl-phthalat) and DBP (Dibutyl-phthalat).

VBM-products that require labeling according to Directive 93/42/EEC are labeled with following symbols:



**Caution:**

Following products contain phthalates. Animal experiments have shown phthalates to be potentially toxic to reproduction. Proceeding from the present state of scientific knowledge, risks for male babies and children cannot be excluded in case of long term exposure. Medical devices containing phthalates should be used only temporarily with pregnant women, nursing mothers, babies and children

**Table 1:** Softener containing medical devices with labeling obligation

REF number	Description	Softener
32-02-002-1	Laryngeal Tube LT-D, Size 2 (Box of 10)	DEHP
32-02-025-1	Laryngeal Tube LT-D, Size 2,5 (Box of 10)	DEHP
32-02-003-1	Laryngeal Tube LT-D, Size 3 (Box of 10)	DEHP
32-02-004-1	Laryngeal Tube LT-D, Size 4 (Box of 10)	DEHP
32-02-005-1	Laryngeal Tube LT-D, Size 5 (Box of 10)	DEHP
32-02-102-1	Laryngeal Tube LT-D, Size 2 (Box of 1)	DEHP
32-02-125-1	Laryngeal Tube LT-D, Size 2,5 (Box of 1)	DEHP
32-02-103-1	Laryngeal Tube LT-D, Size 3 (Box of 1)	DEHP
32-02-104-1	Laryngeal Tube LT-D, Size 4 (Box of 1)	DEHP
32-02-105-1	Laryngeal Tube LT-D, Size 5 (Box of 1)	DEHP
32-02-209-1	Emergency LT-D Set	DEHP
32-06-003-1	Laryngeal Tube LTS-D, Size 3 (Box of 10)	DEHP
32-06-004-1	Laryngeal Tube LTS-D, Size 4 (Box of 10)	DEHP
32-06-005-1	Laryngeal Tube LTS-D, Size 5 (Box of 10)	DEHP
32-06-103-1	Laryngeal Tube LTS-D, Size 3 (Box of 1)	DEHP
32-06-104-1	Laryngeal Tube LTS-D, Size 4 (Box of 1)	DEHP
32-06-105-1	Laryngeal Tube LTS-D, Size 5 (Box of 1)	DEHP
32-06-209-1	Emergency LTS-D Set	DEHP
80-12-010	Reservoir bag for single use, 2600 ml	DEHP
80-12-015	Reservoir bag for single use, 1800 ml	DEHP
80-12-020	Reservoir bag for single use, 600 ml	DEHP
20-10-666	Pressure hose	DEHP

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Following listed products are an assembly of components, of which one or more components contains phthalates. These components are labeled with the required symbol according to Directive 93/42/EEC.

**Table 2:** Medical devices that contain softener containing components with labeling obligation

REF number	Description	Labeled phthalate containing components	Softener
30-65-001	Difficult Airway Bag LT-D	32-02-003-1, 32-02-004-1, 32-01-005-1 LT-D Size 3 to 5	DEHP
30-65-002	Difficult Airway Bag LTS-D	32-06-003-1, 32-06-004-1, 32-06-005-1 LTS-D Size 3 to 5	DEHP
30-70-001	Oxysafety Standard	80-12-010 Reservoir Bag	DEHP
30-75-001	Oxysafety Standard	80-12-010 Reservoir Bag	DEHP
30-75-020	Bag with accessories for Oxysafety	80-12-010 Reservoir Bag	DEHP
30-80-001	Emergency Bag Standard	80-12-010 Reservoir Bag	DEHP
30-80-003	Emergency Bag Standard	80-12-010 Reservoir Bag	DEHP
80-10-161	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
80-10-261	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
80-10-262	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
80-10-290	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
80-10-290-F	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
80-10-291	Resuscitation bag – Set for Children in a case	80-12-015 Reservoir Bag	DEHP
80-10-295	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
80-10-296	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
80-10-361	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP
80-10-390	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP
80-10-390-F	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP
80-10-390S1	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP
80-10-390S2	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP
80-10-390S3	Resuscitation bag – Set for Babies with PEEP	80-12-020 Reservoir Bag	DEHP
80-10-391	Resuscitation bag – Set for Babies in a case	80-12-020 Reservoir Bag	DEHP
80-10-392	Resuscitation bag – Set for Babies in a case	80-12-020 Reservoir Bag	DEHP
80-10-395	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP

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REF number	Description	Labeled phthalate containing single products	Softener
80-10-396	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP
82-10-190	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
82-10-190-F	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
82-10-190S1	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
82-10-191	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
82-10-191-F	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
82-10-195	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
82-10-196	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
82-10-290	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
82-10-290-F	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
82-10-291	Resuscitation bag – Set for Children in a case	80-12-015 Reservoir Bag	DEHP
83-10-191	Resuscitation bag	80-12-010 Reservoir Bag	DEHP
85-10-190	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
85-10-190-F	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
85-10-191	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
85-10-191-F	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
85-10-194	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
85-10-194-F	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
85-10-195	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
85-10-196	Resuscitation bag – Set for Adults	80-12-010 Reservoir Bag	DEHP
85-10-290	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
85-10-290-F	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
85-10-291	Resuscitation bag – Set for Children in a case	80-12-015 Reservoir Bag	DEHP
85-10-295	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
85-10-295-F	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
85-10-296	Resuscitation bag – Set for Children	80-12-015 Reservoir Bag	DEHP
85-10-390	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP
85-10-390-F	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP
85-10-391	Resuscitation bag – Set for Babies in a case	80-12-020 Reservoir Bag	DEHP
85-10-395	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP
85-10-396	Resuscitation bag – Set for Babies	80-12-020 Reservoir Bag	DEHP