



**Overview of Ambu's Medical Devices in relation to content of Latex and REACH Regulated SVHC substances.**












According to the European Chemical regulation (REACH) Ambu is obligated to inform about the products containing SVHC substances (Substances of Very High Concern) in the concentrations above 0.1% (w/w).









The European Medical device directive requires labeling if the medical devices:




- Contain classified phthalates, which are classified and
- are intended to administer and or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances.

The table below provides an overview on all Ambu Medical Devices in relation to content of REACH Regulated SVHC substances in concentrations above 0.1%. The table also includes information on which products that are made with Natural Rubber Latex. Ambu products presented in this list will be labeled as indicated below.

Product	Contents of SVHC above 0.1% (w/w) and description of substance	Natural Rubber Latex	Symbol on the product label
<b>Cardiology and Neurology</b>			
Ambu® BlueSensor Electrodes	No	No	
Ambu® WhiteSensor Electrodes	No	No	
Ambu® Neuroline Electrodes	No	No	
Ambu® Neuroline Corkscrew Electrode	No	No	
Ambu® Neuroline Monopolar and Concentric Cables	No	No	
Ambu® Neuroline Probes	No	No	
Ambu® Neuroline Cup electrodes	No	No	
Ambu® Snap Clip	No	No	
Ambu® Skin Prep	No	No	
Ambu® Myoguide	No	No	
<b>Flexible Scopes</b>			
Ambu® aScope™ 3	No	No	
Ambu® aScope™ 4 Broncho	No	No	
Ambu aScope™ 4 RhinoLaryngo Intervention	No	No	
Ambu® aView™	No	No	
Ambu® aScope BronchoSampler™	No	No	
Ambu® aScope BronchoSampler™ SC	No	No	
<b>Airway Management</b>			
King Vision Video Laryngoscope	No	No	

Product	Contents of SVHC above 0.1% (w/w) and description of substance	Natural Rubber Latex	Symbol on the product label
King Vision aBlade video laryngoscope	No	No	
King Vision Video Out Cable	No	No	
VivaSight-DL	Yes, contain DEHP (CASRN 117-81-7)	No	
VivaSight-SL	Yes, contain DEHP (CASRN 117-81-7)	No	
VivaSight-EB	Yes, contain DEHP (CASRN 117-81-7)	No	
<b>Anaesthesia</b>			
Dual Limb Breathing Circuits	Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling	No	
King F2	Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling	No	
King Flex2	Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling	No	
King Universal F	Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling	No	
King Universal F Flex	Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling	No	
King Ped F2 and King Flex 2 - Pediatric Breathing Circuits	Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling	No	
King Jackson Rees and King Mapleson	Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling	No	
King Transport and PACU Kits	Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling	No	
King Breathing Bags (STD and colored)	Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling	No	
HMEs and Filters	No	No	
Ambu® aFlow Corrugated Anaesthesia Circuits	No	No	
Ambu® aFlow Coaxial Circuits	No	No	
Ambu® aFlow Extendible Anaesthesia Circuits	No	No	
Ambu® aFlow Heated Wire Circuits	No	No	
Ambu® aFlow Setpump Divided Single Limb Circuit	No	No	
Ambu® aFlow Semi-Closed Circuit and Nitrous Oxide and Oxygen Delivery Circuit	No	No	
Ambu® aFlow Smoothbore Anaesthesia Circuits	Yes, contain DOTE (CASRN 15571-58-1) if circuits have 15mm or 19 mm smoothbore PVC	No	

Product	Contents of SVHC above 0.1% (w/w) and description of substance	Natural Rubber Latex	Symbol on the product label
Ambu® catheter mounts	Yes, contain DOTE (CASRN 15571-58-1) if catheter mounts have 15mm smoothbore PVC	No	
Ambu® aFlow CO2 Sampling Line	No	No	
Ambu® aFlow Connectors	No	No	
Ambu aFlow Breathing Bags	No	No	
Ambu aFlow Filters	No	No	
Ambu® Disposable Face mask	No	No	
Ambu® Open Cuff Silicone Mask	No	No	
Ambu® Silicone Face Mask	No	No	
Ambu® Transparent Face Mask	No	Yes	
Ambu® UltraSeal	No	No	
Ambu® King Mask	No	No	
Ambu® AuraOnce™	No	No	
Ambu® AuraFlex™	No	No	
Ambu® AuraStraight™	No	No	
Ambu® Aura-i™	No	No	
Ambu® Aura40™	No	No	
Ambu® AuraGain	No	No	
Ambu® Cuff Pressure Gauge	No	No	
<b>Emergency Care</b>			
Ambu® SPUR II	No	No	
Ambu® Mark IV	No	No	
Ambu® Mark IV Baby	No	No	
Ambu® Military Mark III	No	No	
Ambu® Oval Silicone resuscitator	No	No	
Ambu® Oval Plus Silicone resuscitator	No	No	
Ambu® PEEP Valves	No	No	
Ambu® Disposable Pressure Manometer	No	No	

Product	Contents of SVHC above 0.1% (w/w) and description of substance	Natural Rubber Latex	Symbol on the product label
Ambu® TubeChek	Yes, contain DEHP (CASRN 117-81-7)	No	
Ambu® ET Tube holder	No	No	
Ambu® LifeKey	No	Yes*	
Ambu® ResKey	No	Yes*	
Ambu® Res-Cue Mask	No	No	
Ambu® Suction Booster	Yes, contain DEHP (CASRN 117-81-7)	No	
Ambu® Res-Cue Pump	No	No	
Ambu® Twin Pump	No	No	
Ambu® Uni-Suction Pump	No	No	
Ambu® Perfit ACE	No	No	
Ambu® Mini Perfit ACE	No	No	
Ambu® Perfit	No	No	
Ambu® Redi-ACE Adult	No	No	
Ambu® Redi-ACE Mini	No	No	
Ambu® Head Wedge	No	No	

\*No patient contact with the part containing natural rubber latex