



## **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 products containing listed SVHC substances (Substances of Very High Concern) in concentrations above 0.1% (w/w). See the following website for the current version of the SVHC list: <http://echa.europa.eu/web/guest/candidate-list-table>

The table below provides an overview of all Ambu Medical Devices in relation to content of REACH Regulated SVHC substances in concentrations above 0.1% (w/w). The table also includes information on which products are made with Natural Rubber Latex. All products that has “No” in the SVHC column (column 2) does not contain any substances currently on the SVHC list.

Product	Contents of SVHC above 0.1% (w/w) and description of substance	Natural Rubber Latex
Ambu® BlueSensor Electrodes	No	No
Ambu® WhiteSensor Electrodes	No	No
Ambu® Neuroline Electrodes	No	No
Ambu® Neuroline needles (Inoject, concentric, monopolar, subdermal, subdermal twisted)	No	No
Ambu® Neuroline Ground	No	No
Ambu® SkinFix	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
Ambu® aScope™ 3	No	No
Ambu® aScope™ 4 Broncho	No	No
Ambu® aScope™ 4 Broncho Sampler Set	No	No
Ambu® aScope™ 4 RhinoLaryngo	No	No
Ambu® aScope™ 4 Cysto	No	No
Ambu® aScope™ 5 Cysto HD	No	No
Ambu® aScope™ 5 Broncho HD	No	No
Ambu® aScope™ 5 Broncho	No	No
Ambu® aScope™ 5 Broncho HD Sampler Set	No	No
Ambu® aScope™ 5 Uretero	No	No
Ambu® aScope™ Duodeno	No	No
Ambu® aScope™ Duodeno 2	No	No
Ambu® aScope™ Gastro	No	No

Product	Contents of SVHC above 0.1% (w/w) and description of substance	Natural Rubber Latex
Ambu® aScope™ Gastro Large	No	No
Ambu® aScope BronchoSampler™ 60 SC	No	No
Isiris™α	No	No
Ambu® aView™	Yes, Lithium battery contains 1,3-propanesultone (CASRN 1120-71-4)	No
Ambu® aView™ 2 Advance	Yes, Lithium battery contains 1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME) (CASRN 110-71-4)	No
Ambu® aBox Duodeno	No	No
Ambu® aBox™ 2	No	No
King Vision Video Laryngoscope	No	No
King Vision aBlade video laryngoscope	No	No
King Vision Video Out Cable	No	No
VivaSight-DL	No	No
Ambu® VivaSight™ 2 DLT	No	No
Ambu® VivaSight™ 2 DLT Kit	No	No
VivaSight-SL	No	No
VivaSight-EB	No	No
Ambu® VivaSight™ 2 Endobronchial Blocker Tube	No	No
King Dual Limb Breathing Circuits	No	No
King F2	No	No
King Flex2	No	No
King F Flex2	No	No
King Universal F	No	No
King Universal F Flex	No	No
King Universal F Flex2	No	No
King Ped F2 and King Flex 2 - Pediatric Breathing Circuits	No	No
King Jackson Rees and King Mapleson	No	No
King Transport and PACU Kits	No	No
King Breathing Bags (STD and colored)	No	No
HMEs and Filters	No	No
Xenon	No	No
Sampling Line	No	No

Product	Contents of SVHC above 0.1% (w/w) and description of substance	Natural Rubber Latex
King LTS-D	No	No
Nitric Oxide	No	No
Vent Circuits	No	No
Extension Sets	No	No
Flex Connectors	No	No
Headstraps	No	No
Tube Tree	No	No
Manifolds	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™	Yes, Contains Octamethylcyclotetrasiloxane (CASRN 556-67-2)	No
Ambu® AuraGain	No	No
Ambu® Cuff Pressure Gauge	No	No
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
Ambu® LifeKey	No	Yes*
Ambu® ResKey	No	Yes*
Ambu® Perfit ACE	No	No

<b>Product</b>	<b>Contents of SVHC above 0.1% (w/w) and description of substance</b>	<b>Natural Rubber Latex</b>
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