

# **Declaration of conformity RoHs & REACH**

We hereby declare to be in compliance with the following directives and regulations:

- -DIRECTIVE 2011/65 / EU (RoHS II) and their extensions to medical devices with effect from 22.07.2014
- -Regulation (EC) No 1907/2006 (REACH)
- -Candidate list SVHC
- --Minitial ingredients according to RoH32 / REACH (Annex XVI / XVII and SVHC-Art.33 as well as BPA or latex

### **RoHs - Restriction of Use of Certain Hazardous Substances**

Content Directive 2011/65 / EU:

Substances	Maximum permissible concentration in homogeneous
	Materials in weight percentages
Lead	0, 1%
Mercury	0, 1%
Cadmium	0.01%
Hexavalent chromium	0, 1%
Polybrominated biphenyls (PBB)	0.1%
Polybrominated dipheyl ethers (PBDE)	0.1%

### **Declaration RoHs (2011/65/65)**

We hereby confirm the RoHs conformity, as opposed to our customers, and that the homogeneous materials of our substances listed above are not more than the defined limit values.

#### **REACH**

Contents Regulation (EC) No: 19078/2006 (REACH):

Registration, evaluation, Authorization Restriction of Chemicals

List of "Substances of Very High Concern" SVHC

Http://echa.europa.eu/en/candidate-list-table

- -not reporting SVHC ingredients according to type: 33
- no ingredients according to Annex XVII
- no ingredients according to Annex XIV



## Supplementary declaration of latex / BPA

-No latex present in the delivered products / detectable

Place and date Altusried, 01.01.2019 i.A. Armin Janusch Managing Director