

**Declaration of Conformity
To
Registration, Evaluation, Authorisation and Restriction of Chemicals**

This declaration of conformity is issued under the sole responsibility of the manufacturer:

AKRUS GmbH & Co. KG
Otto-Hahn-Str. 3
25337 Elmshorn
Germany

Second production site:
Otto-Hahn-Str. 14
25337 Elmshorn
Germany

Object of the declaration includes all products produced by AKRUS GmbH & Co. KG.
The object of the declaration described above is in conformity with REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Amended and corrected version 2023-06-29 released until date of signature of this declaration.

AKRUS GmbH & Co. KG and its suppliers have reviewed the lists of Substances of Very High Concern (SVHC), published in accordance with Article 59 paragraph 10 of REACH Regulation (EC) No 1907/2006, in accordance with all Articles of the REACH Regulation and Restricted List, detailed in Annex XVII and Annex XIV of REACH.
All products supplied by AKRUS GmbH & Co. KG are according to the current candidate list:

REACH – Substance of Very High Concerns (SVHC) Candidate List updated on 2023-06-14, number of substances on the candidate list: 235.

This statement is to certify that the parts manufactured by AKRUS GmbH & Co. KG are fully compliant with REACH – SVHC Directives with its SCIP database submission number.

AKRUS GmbH & Co. KG, a manufacturer of medical devices with risk class I and further products as industry supplier, is classified as a “downstream user” in the sense of REACH regulation 1907/2006. Duties and liabilities for pre-registration or registration based on the production and bringing into circulation of substances and chemicals are therefore not effective to Akrus GmbH & Co KG.

Our products are finished goods and therefore not to be defined as substance or preparation. Furthermore, the items manufactured by Akrus GmbH & Co KG are non chemical goods. They do not emit any substances as long as operated under normal and foreseeable conditions. Consequently, article 7 of the regulation does not apply to Akrus GmbH & Co KG.

To continuously provide our customers with reliable and safe products, Akrus GmbH & Co KG ensure that our suppliers comply with all requirements related to the usage of chemical substances and materials. Thus, we ensure that no substances or materials from the list of substances with very high concerns (SVHC) are used in production of the products.

The declaration is based on information from sources which we believe are reliable. Product users are responsible for determining the applicability of REACH and other related environmental regulations based on their individual usage of the final product.

Elmshorn, the 2023-08-03

A handwritten signature in black ink that reads 'Roman Gartz'.

Dipl.-Ing. Roman Gartz
(Quality Management Officer, Person Responsible for Regulatory Compliance)