

Declaration of Substances of Very High Concern (REACH)

30.04.2024

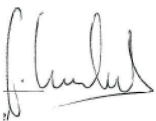
To whom it may concern,

According to Article 33 of the Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and restrictions of Chemicals (REACH), the Christoph Miethke GmbH & Co.KG (MIETHKE) has the duty to communicate the presence of substances of very high concern (SVHC) as provided by our suppliers to their customers. The current list of SVHC (candidate list) is published in article 59 of the REACH regulation and can be found on <https://echa.europa.eu/de/candidate-list-table>.

MIETHKE is a downstream user and does not import quantities of more than 10 tons per year of substances of very high concern. Therefore, there exists no registration obligations for MIETHKE.

On the following page(s) of this document, we provide an overview of all our Shunt System Components, that contain any Substance of Very High Concern (SVHC) above the threshold of 0.1 %.

With kind regards,



Jörg Knebel
Vice President Quality Management

Table 1: Reach Declaration for Miethke Shunt System Components

| Type | Shunt System Component | SVHC according to REACH Regulation | | | | | |
|--|------------------------------|---|--|---|---------------------------|---|---|
| | | Octamethylcyclo-tetrasiloxan (D4) CAS-No. 556-67-2 | Decamethylcyclo-pentasiloxane (D5) CAS No. 541-02-6 | Dodecamethylcyclo - hexasiloxane (D6) CAS No. 540-97-6 | Lead CAS No. 7439-92-1 | 1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME) CAS-No. 110-71-4 | 1,3-propanesultone CAS-No. 1120-71-4 |
| Valve | DUALSWITCH VALVE | | X | X | | | |
| | DUALSWITCH VALVE LP | | X | X | | | |
| Reservoir/ Port | Prechamber | | X | X | | | |
| | Pediatric Prechamber | | X | X | | | |
| | CONTROL RESERVOIR | | X | X | | | |
| | Pediatric CONTROL RESERVOIR | | X | X | | | |
| | CSF-Port | | X | X | | | |
| | Burrhole Port | | X | X | | | |
| | Pediatric Burrhole Port | | X | X | | | |
| | Burrhole Reservoir | | X | X | | | |
| | Pediatric Burrhole Reservoir | | X | X | | | |
| | SPRUNG RESERVOIR | | X | X | | | |
| | Pediatric SPRUNG RESERVOIR | | X | X | | | |
| | ETOU RESERVOIR | | X | X | | | |
| | M.scio® | | X | X | | | |
| McLANAHAN RESERVOIR | | X | X | | | | |
| Catheter and other Silicone Products | Ventricular Catheter | X | X | X | | | |
| | Peritoneal Catheter | | X | X | | | |
| | Anti-Kink Catheter | | X | X | | | |
| | Lumbar Catheter | X | X | X | | | |
| | XABO® Ventricular Catheter | X | X | X | | | |

| Type | Shunt System Component | SVHC according to REACH Regulation | | | | | |
|-------------|--|--|---|--|---------------------------|---|---|
| | | Octamethylcyclotetrasiloxan (D4) CAS-No. 556-67-2 | Decamethylcyclopentasiloxane (D5) CAS No. 541-02-6 | Dodecamethylcyclohexasiloxane (D6) CAS No. 540-97-6 | Lead CAS No. 7439-92-1 | 1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME) CAS-No. 110-71-4 | 1,3-propanesultone CAS-No. 1120-71-4 |
| | XABO® Peritoneal Catheter | | X | X | | | |
| | Valve Board | X | X | X | | | |
| | Suture Wings (part of Lumbar Catheter Set) | | | | | | |
| Instruments | proGAV® Instruments | | | | X | | |
| | proSA® Instruments | | | | X | | |
| | proGAV 2.0 Instruments | | | | X | | |
| | M.scio® Reader Unit Set | | | | X | X | X |