

Declaration of Substances of Very High Concern (REACH)

25.01.2022

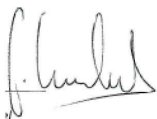
To whom it may concern,

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		
		Decamethylcyclopentasiloxane (D5) CAS No. 541-02-6	Dodecamethylcyclohexasiloxane (D6) CAS No. 540-97-6	Lead CAS No. 7439-92-1
Valve	DUALSWITCH VALVE		X	
	DUALSWITCH VALVE LP		X	
Reservoir/ Port	Prechamber		X	
	Pediatric Prechamber	X	X	
	CONTROL RESERVOIR		X	
	Pediatric CONTROL RESERVOIR	X	X	
	CSF-Port		X	
	Burrhole Port		X	
	Pediatric Burrhole Port	X	X	
	Burrhole Reservoir		X	
	Pediatric Burrhole Reservoir	X	X	
	SPRUNG RESERVOIR		X	
	Pediatric SPRUNG RESERVOIR	X	X	
	ETOU RESERVOIR		X	
	M.scio®		X	
	McLANAHAN RESERVOIR		X	
Catheter	Ventricular Catheter	X	X	
	Peritoneal Catheter		X	
	Anti-Kink Catheter		X	
Instruments	proGAV® Instruments			X
	proSA® Instruments			X