

Biomedizinische Instrumente und Produkte GmbH

BIP GmbH I Am Brand 1 I D-82299 Türkenfeld

To all BIP customers

Türkenfeld, 24.11.2025

Customer declaration on REACH, RoHS, Latex

Dear Customer,

REACH

We hereby inform you that only the following articles supplied by us contain a substance of very high concern on the SVHC candidate list (since January 2024) above 0.1 % according to Art. 33 of the REACH Regulation (Regulation (EC) No. 1907/2006):

vPvB-substance (= very persistent and very bioaccumulative):

 2-(2-Hydroxy-5-tert-octylphenyl)benzotriazol Concentration [mass.-%]: ≥ 0,1 - < 0,3 CAS-Nr.: 3147-75-9

Affected products:

Plastic components including overmolded needles (cannula, stylet, mandrel) of all BIP medical devices of the following product groups:

Biopsy Devices, disposable – only pre-mounted coaxial cannula in type HC-TX

(upon LOT 0325)
- Biopsy Needles (upon LOT 1224)
- Fine Biopsy Needles (upon LOT 0325)
- Coaxial Cannulas (upon LOT 0325)
- Marking Clips (upon LOT 0325)
- Localization Wires (upon LOT 0325)

NOTE: A concentration of more than 0.1 % weight by weight (w/w) of this SVHC in a product does not pose a risk to humans or the environment when handled properly and has no restriction on the safe use of BIP medical devices.

info@bipmedical.com

www.bipmedical.com

Bankverbindungen



Biomedizinische Instrumente und Produkte GmbH

Necessary environmental protection measures (disposal):

Do not allow products to enter waters, waste water or the soil.

Our suppliers are obliged either by law or by contract to inform us without request if the products they supply contain a SVHC substance above 0.1%.

If we receive information in this regard from our suppliers and thereby become aware that the 0.1 % weight by weight limit for a SVHC substance is exceeded in our products, we will update this REACH declaration.

Accordingly, all other sales products from BIP GmbH are free from substances on the current SVHC candidate list (as of 05-Nov-2025).

The data has been compiled to the best of our knowledge. However, we are dependent on the assistance of our suppliers with regard to the completeness of data.

RoHS

The products supplied by us do not fall under the RoHS directive, as they do not contain electrics / electronics.

Latex

We confirm that BIP medical devices and supplied products do not contain latex or latexbased compounds. This declaration applies to all materials used in the manufacture and packaging of the product(s).

Kind regards,

Thomas Heske

Managing Director (CEO)

www.bipmedical.com